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GSA-39

27-NP

November 1, 2006

Patricia N. Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
USDA
3101 Park Center Drive
Room 528
Alexandria, VA 22302

RE: Docket ID Number 0584-AD77, WIC Food Packages Rule

Dear Ms. Daniels:

The Massachusetts WIC Nutrition Program strongly and enthusiastically supports the USDA issued proposed rule governing the WIC Food Packages published in the Federal Register on August 7, 2006.

The intent of the revised regulations is to improve the nutritional health of all WIC participants. The revisions are grounded in sound science, aligned with the *2005 Dietary Guidelines for Americans*, support the current infant feeding practice guidelines of the American Academy of Pediatrics, and support the establishment of successful long-term breastfeeding. The proposed food packages provide WIC participants with a wider variety of food choices, allow state agencies greater flexibility in offering food packages that accommodate participants' cultural food preferences, and address the nutritional needs of our nation's most vulnerable women, infants and children.

The proposed rule reflects recommendations made by the Institute of Medicine (IOM) of the National Academies in its report, "WIC Food Packages: Time for a Change." It follows the advice of the Institute, which stated that the WIC Program needs to respond to changes in nutrition science, demographics, technology, and the emerging health concerns in the WIC community. The changes in the proposed rule are consistent with nutrition education promoting healthier lifestyles and food selections to reduce the risk for chronic diseases and to improve the overall health of WIC's diverse population. The Department's aim is to add new foods while preserving cost neutrality—to cover the cost of the new

~~foods, the proposed adjustments to juice, eggs and milk are highly acceptable. We believe that WIC~~
clients will be pleased that there will be more choices in the foods offered.

Massachusetts WIC has the following recommendations regarding the proposed rule.

Breastfeeding

The proposed rule aims to support breastfeeding, with appropriate complementary foods after the first six months, until the infant's first birthday.

- We *do not support* the recommendation to pilot test the food package for the partially breastfeeding woman. With a delay in implementation of the partially breastfeeding package, we believe that many women will simply choose to formula feed in order to benefit from the changes to the new fully formula feeding package. We recommend that the fully breastfeeding, partially breastfeeding and fully formula feeding woman's food package changes be implemented concurrently.
- We urge that the dollar amount for fruits and vegetables provided to the fully breastfeeding woman be increased to \$10, matching the IOM recommendation, for at least the first six months post partum. This would provide stronger incentive and support for breastfeeding in the period of time prior to the addition of complementary foods for fully breastfeeding infants at six months. If the USDA is unable to match the IOM recommendations for this group of women for this six month period, they should, at a minimum, allow States to act within the limits of their food funding to exceed the current maximum dollar amount for the fruits and vegetables vouchers for women within the first six months of breastfeeding.
- We would also suggest that States be given the option to provide the breastfeeding infant, in the first month, with 1) no formula, or 2) one can of powdered formula as recommended in the IOM Report. States would incorporate their option into their existing breastfeeding policies and procedures. An evaluation of the impact of these options on a mother's breastfeeding status will also allow USDA to determine an appropriate future course of action.
- State agencies will also require additional resources to provide enhanced breastfeeding support, peer counseling services and pumps to participants in order to ensure that WIC mothers feel comfortable foregoing formula within the first month and thereafter to help ensure breastfeeding success and optimal nutrition for their infants. WIC is the only national program that provides this level of breastfeeding education and support to the WIC population and must ensure that these exciting changes to promote breastfeeding do not have the converse effect because mothers are afraid to give up all WIC formula benefits.

Soy Products

The proposed food packages offer calcium-set tofu as well as calcium- and vitamin D-rich soy beverages as partial substitutions and alternatives for milk. These alternatives will prove to be particularly beneficial to those WIC participants who suffer the medical consequences of milk protein allergy, lactose maldigestion, and those with cultural preferences.

- Currently, there are no calcium-fortified soy-based beverages on the market that meet the proposed protein and potassium standards. We urge FDA- and industry-standard levels of 6.25 grams of protein and 250 milligrams of potassium per 8 ounce serving as alternative minimum standards in order for the WIC food packages for women and children to be able to include soy.
- We also recommend that children be able to receive soy products without the requirement of medical documentation. The consumption of soy beverages and tofu for children can be a cultural/personal preference as well as a medical necessity. Since State policies and procedures for services and follow-up to medically diagnosed conditions will continue to be in place, this proposed rule will place an undue burden on the medical community and WIC service delivery systems and delay access to an important calcium source for WIC children.

Whole Grains

The proposed rule's establishment of a 51% whole grain requirement for breakfast cereals and inclusion of whole grain bread and other grains for all children and pregnant and breastfeeding women is consistent with the *2005 Dietary Guidelines for Americans* which recommend that refined grains be replaced with whole grains.

- Massachusetts WIC recommends that USDA increase the allowable amount of whole grain bread from 16 ounces to one loaf up to 24 ounces, an amount consistent with the sizes available in stores. Data from Interstate Bakeries indicate that 56 percent of whole wheat/whole grain loaves are sold in 24 ounce loaves, and 25 percent are sold in 20 ounce loaves.
- In order to accommodate the medical needs of certain participants, we support the IOM recommendation to allow States to make substitutions for "wheat-free" and "gluten-free" cereals based on a medical prescription and urge the Department to include such a provision in the final rule.

Fruits and Vegetables

The proposed rule provides for complementary infant food fruits and vegetables at six (6) months of age in varying amounts for those infants who are fully breastfeeding, partially breastfeeding or fully formula feeding as well as infant food meats for fully breastfeeding infants. Children and women participants will also benefit from the addition of fruits and vegetables through "cash-value" vouchers to purchase fresh and processed fruits and vegetables in the proposed amounts of \$8 for women and \$6 for children.

The food package recommendations support scientific research findings, which suggest that increasing fruits and vegetables is associated with reduced risk for obesity and chronic diseases such as cancer, stroke, cardiovascular disease, and type 2 diabetes. Fruits and vegetables added to the diet also promote adequate intake of priority nutrients such as Vitamins A, C, folate, potassium and fiber.

- In addition to the recommendation to increase the dollar amount of cash-value food instruments for fruits and vegetables to \$10 for fully breastfeeding women for a minimum of the first six months post partum, USDA should act to allow for full implementation of the IOM recommendation of \$10 cash-value instruments for all women and \$8 for children. To implement this recommendation while maintaining cost neutrality, States should have the option to:

- ~~○ Omit juice from the food packages for all children, a cost-saving measure that the medical and dental communities would fully support.~~
- Reduce the amount of whole grains a child receives to one loaf of bread or one pound of a whole grain substitute to make the children's food package consistent with women's and still maintain current dietary guidelines.

Cutting corners with the fruit and vegetable cash-value instruments will lead to reduced health benefits for WIC mothers and children. WIC's success has been in saving long-term healthcare costs. Making this modest investment will assure healthcare savings in the future.

Vendor Regulations

- We strongly recommend that the minimum vendor stocking requirements for fruits and vegetables be determined at the discretion of the WIC State agencies.

State flexibility to promote produce selections that are locally accessible, culturally appropriate, affordable, and practical for various household situations - such as storage, preparation and cooking options - is paramount. Flexibility will give States the capability to partner with vendors to promote the maximum number and variety of produce items. Setting an arbitrary vendor stocking level at two items as suggested in the proposed rule will not encourage State agencies or vendors to provide the wide variety of fruits and vegetables purchased by WIC consumers as demonstrated in the three highly successful pilot projects recently conducted in California and New York.

- Massachusetts WIC recommends that the USDA allow States to utilize existing Farmers' Market Nutrition Program vendor certification procedures for authorizing Farmers' Markets to participate in the WIC fruit and vegetable cash-value voucher program. Massachusetts WIC supports The National Association of Farmers' Market Nutrition Program's recommendation to utilize the existing FMNP structure and personnel for vendor authorization and compliance. Taking advantage of FMNP resources would greatly reduce the administrative burden on State WIC agencies and maximize the opportunities for small, local growers to participate in the WIC program. Without these changes, the proposed rule requirements would make the participation of farmers impossible to implement for the following reasons:
 - Farmers' markets do not, and can not, meet the existing federal selection criteria with regards to the variety and quantity of foods that must be stocked.
 - Farmers generally do not sell from fixed sites and current vendor regulations only allow mobile stores for the purpose of meeting special needs as described in each State agency's State Plan.
 - Farmers would be held to current WIC vendor monitoring and auditing requirements, which do not fit their operational models.
- Massachusetts WIC urges USDA to exempt farmers' market vendors from the above-50 percent vendor cost containment regulations. One of the benefits of the cash-value fruits and vegetables voucher system is that vendors and farmers would have to maintain competitive pricing in order to compete for WIC fruit and vegetable dollars. Subjecting farmers to the above-50 percent vendor regulations would be an undue and unnecessary burden on farmers and on the States. Furthermore,

sanctions on farmers market that sell more than 50 percent of their produce through WIC would prevent farmers' markets from locating in low-income urban neighborhoods where the challenge of accessing fresh produce is the greatest.

Voucher Redemption

- Massachusetts WIC recommends that USDA give State agencies the discretion to determine the dollar denomination of the fruit and vegetable cash-value vouchers. It is essential that State agencies determine the dollar value of the cash-value vouchers in partnership with vendors to assure appropriate redemption levels and to save already tight Nutrition Services dollars. Printing of multiple vouchers in small, two-dollar denominations is costly and counter productive.
- USDA must give State agencies the flexibility to work with existing WIC vendors and the FMNP to develop and implement effective food instrument redemption procedures for fruits and vegetables cash-value vouchers that minimize administrative costs, processing errors, and are responsive to current WIC vendor and FMNP systems.

Rounding Up

- In addition to giving States the option to round-up for cans of formula, jars of baby food and infant cereal, USDA should allow each State to develop its own methodology for how best to round up, since effective methods will vary depending on State information systems and processes for building food instruments.

Categorical Tailoring and Substitution Requests

- Massachusetts WIC is inalterably opposed to the removal of the State option to categorically tailor or propose food substitutions. There are rapid changes in food industry, science, demographics and other factors in today's environment, and State agencies will, of consequence, need to submit proposals for cultural accommodations or categorical tailoring in the future. USDA's history of regulatory review and revisions to the WIC food packages substantiates the critical need for this flexibility. It is essential that States be allowed the ability to revise food lists to keep pace with the needs of their participants.

Implementation

Massachusetts WIC recognizes that implementing the proposed rule will require good planning and effective communication. Implementation strategies to maximize benefits at every level will need to be inclusive and carefully crafted to achieve success. There is great excitement and anticipation among State agencies regarding the promulgation of a final rule revising the WIC food packages and State agencies, without exception, are looking forward to fully implementing the proposed rule.

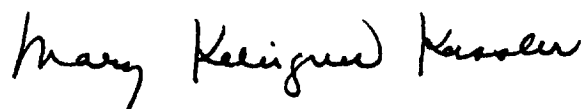
- We recommend that USDA partner with State agencies and the National WIC Association to assure a reasonable and flexible implementation timeframe from the date of publication of the final rule.

~~In closing, Massachusetts WIC enthusiastically and strongly supports the proposed rule. We are~~
convinced that it will support participant choice and focus attention on chronic disease prevention and control. The proposed food packages will provide greater amounts of all of the priority nutrients currently identified as needed by the WIC population. They will supply a reliable and culturally acceptable source of supplemental nutritious foods as well as promote and support breastfeeding. Equally important, the proposals will provide WIC professionals with the necessary tools to reinforce the nutrition education messages and promote healthier food choices. In addition, our outlined recommendations will serve to minimize vendor stock requirements, reduce the administrative burden on States and local agencies, and encourage the growth of Farmers' Markets.

WIC is our nation's premier public health nutrition program. The long-term benefits of providing participants with fruits and vegetables, lower fat dairy products and whole grains, as well as additional incentives for fully breastfeeding women will greatly aid WIC in improving the life-long health of our most vulnerable women, infants and children.

We look forward to working closing with USDA to fully implement the proposed rule and urge finalization of the rule by no later than the spring of 2007.

Sincerely,

A handwritten signature in black ink, reading "Mary Kelligrew Kassler". The signature is written in a cursive, flowing style.

Mary Kelligrew Kassler
Director, Nutrition Division



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 Phone 573-751-6400 FAX 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Julia M. Eckstein
Director



Matt Blunt
Governor

11-02-06 email from Lyn Konstant [Lyn.Konstant@dhss.mo.gov]

GSA-40

November 2, 2006

Patricia N. Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
USDA
3101 Park Center Drive
Room 528
Alexandria, VA 22302

RE: "Docket ID Number 0584-AD77, WIC Food Packages Rule

Dear Ms. Daniels:

The Missouri WIC Program, administered by the Missouri Department of Health and Senior Services, supports the USDA issued proposed rule governing the WIC Food Packages published in the Federal Register on August 7, 2006.

The intent of the revised regulations is to improve the nutritional health of all WIC participants. The revisions are grounded in sound science and aligned with the *2005 Dietary Guidelines for Americans*. The proposed food packages provide WIC participants with a wider variety of food choices, allow state agencies greater flexibility in offering food packages that accommodate participants' cultural food preferences and address the nutritional needs of our nation's most vulnerable women, infants and children.

The changes in the proposed rule are consistent with nutrition education promoting healthier lifestyles and food selections to reduce the risk for chronic diseases and to improve the overall health of WIC's diverse population. USDA's aim to add new foods while preserving cost neutrality appears to work from the food cost standpoint. However, it does appear that there will be additional administrative cost burden if the State agency is required to have vendor contracts with farmers and farmers' markets throughout the state to allow the WIC participants to purchase fresh produce from these vendors. Our concern is described in more detail later in the letter.

To cover the cost of the new foods, WIC will pay for less juice, eggs and milk that have been staples of this extremely successful public health nutrition program, which helps feed more than half the infants born in the United States. Although yogurt is a very healthy substitute for milk, we agree with allowing calcium rich tofu and soy beverage rather than the more expensive

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yogurt as a cow's milk alternative. The fortified soy products will also offer additional milk substitutes for WIC participants allergic to cow's milk.

The proposed rule aims to support breastfeeding for the first six months and continued breastfeeding, with appropriate complementary foods, until the infant's first birthday. *We do not support* the recommendation to pilot test the food package for the partially breastfeeding woman. With a delay in implementation of this package, we believe that many women will simply choose to formula feed. We recommend that the fully breastfeeding, partially breastfeeding and fully formula feeding woman's food package changes be implemented concurrently and at the same time as all other food package changes. WIC breastfeeding rates have increased at a faster rate than in the non-WIC population in the United States in the last decade, although WIC participants do lag behind the general population toward meeting the breastfeeding objectives of Healthy People 2010. We do not want to regress in our breastfeeding rates.

We recommend that States be given the option to provide the breastfeeding infant, in the first month, with 1) no formula, or 2) no formula unless medically indicated, or 3) one can of powdered formula. States would incorporate their option into their existing breastfeeding policies and procedures. We want to ensure that breastfed infants are eligible for Food Packages I and III if medically indicated during the first month.

We oppose USDA's proposed method to "round up" the issuance of formula. The method will be confusing to participants since different numbers of cans are issued every month. It will create administrative burden for local agencies to keep track of number of cans issued the previous food issuance cycle, especially when participants miss an appointment or change from multi-month to monthly issuance cycle when their health status declines.

Under the proposed rule, a breastfeeding woman who requests more than the maximum amount of formula for a partially breastfed infant will not receive a food package, but will count as a participant and receive nutrition education, breastfeeding support, and health referrals. Local WIC agencies will incur the costs of providing these services and certification, but will not be compensated. Additionally, these women may prefer not to participate without a food package.

Proposed Food Package III would not be issued for a suspected, but unconfirmed allergy. We recommend USDA clarify what is meant by "confirmed allergy".

The Proposed Food Packages would require medical documentation for any supplemental foods issued as part of food package III. Since participants with qualifying conditions will be eligible for all supplemental foods, this will help ensure that the health care provider can appropriately manage the participant's special dietary needs.

The proposed rule provides for complementary infant food fruits and vegetables at six (6) months of age in varying amounts for those infants who are fully breastfeeding, partially breastfeeding or fully formula feeding as well as infant food meats for fully breastfeeding infants. Children and women participants will also benefit from the addition of fruits and vegetables through "cash-value" vouchers to purchase fresh and processed fruits and vegetables in the proposed amounts of \$8 for women and \$6 for children. We urge that the dollar amount

provided to the fully breastfeeding woman be increased to \$10 to match the IOM recommendation. This would provide further incentive and support for breastfeeding.

The food package recommendations support scientific research findings, which suggest that increasing fruits and vegetables is associated with reduced risk for obesity and chronic diseases such as cancer, stroke, cardiovascular disease, and type 2 diabetes. Fruits and vegetables added to the diet also promote adequate intake of priority nutrients such as Vitamins A, C, folate, potassium and fiber.

We strongly recommend that the dollar denomination of the fruit and vegetable cash-value vouchers and the minimum vendor stocking requirements for fruits and vegetables be determined at the discretion of the WIC State agencies. State flexibility to promote produce selections that are locally accessible, culturally appropriate, affordable, and practical for various household situations such as storage, preparation and cooking options is very important. Flexibility will give States the capability to partner with vendors to promote the maximum number and variety of produce items. Setting an arbitrary vendor stocking level at two (2) as suggested in the proposed rule will not encourage State agencies or vendors to provide the wide variety of fruits and vegetables purchased by WIC consumers as demonstrated in the three highly successful pilot projects recently conducted in California and New York. It is essential that State agencies determine the dollar value of the cash-value vouchers in partnership with vendors to assure appropriate redemption levels and to save already tight Nutrition Services dollars. Printing of multiple voucher instruments in small denominations is costly and counterproductive.

The proposed food packages offer calcium-set tofu as well as calcium- and vitamin D-rich soy beverages as partial substitutions and alternatives for milk. These alternatives will prove to be particularly beneficial to those WIC participants who suffer the medical consequences of milk protein allergy, lactose maldigestion, and those with cultural preferences. Currently, there are no calcium-fortified soy-based beverages on the market that meet the proposed protein and potassium standards. Accordingly, we urge levels of 6.25 grams of protein and 250 milligrams of potassium per 8 ounce serving as alternative minimum standards in order for WIC women and children to be able to include soy. We also urge that children be able to receive soy products without the requirement of medical documentation. We do not want to burden the health care providers (physicians) by asking them to write a prescription for fortified soy products, when a nutritionist could use his/her critical thinking skills and determine the need for soy vs. cow's milk for the WIC participant.

The proposed rule to include whole grain bread and other grains for all children and pregnant and breastfeeding women is consistent with the *2005 Dietary Guidelines for Americans*, which recommend that refined grains be replaced with whole grains. In order to accommodate the medical needs of certain participants, we support the IOM recommendation to allow States to make substitutions for "wheat-free" cereals based on a medical prescription and urge the Department to include such a provision in the final rule.

We recommend clearly defining whole grain breads and cereals. The standard of identity is for whole wheat bread, not whole grain bread. Is the assumption that any product that states "whole wheat bread" is acceptable? This needs to be clarified in the final rule.

Missouri WIC opposes USDA's proposal to remove the State option to categorically tailor or propose food substitutions. States should be allowed the flexibility to revise food lists to keep pace with the needs of the participants and the rapid changes in food industry.

One area that Missouri has serious concerns relates to authorizing eligible vendors. The clause that Missouri does not agree with is found in (E)(4)(c) in the first paragraph on page 44799, which states:

c. Farmers' Markets. The Department proposes to allow the State agency to authorize farmers at farmers' markets to accept the WIC cash-value food instrument for fruits and vegetables. Such markets would have to meet vendor selection criteria specified at 246.12(g)(3) and would be subject to the vendor agreement requirements outlined in 246.12 (h) (3).

This action by USDA would create an undue administrative financial burden on Missouri to administer new vendor contracts if the farmers' markets and farmers were authorized. The addition of these contracts will dramatically increase costs related to maintaining and monitoring these vendors as well as creating a need to hire additional staff to accomplish the monitoring of these new vendors. By adding the 2,500 farmers from the 112 active farmers' markets in Missouri, the number of vendors would increase to approximately 3,220 WIC vendors.

By including the statement *c. Farmers' Markets* in the food package revisions, USDA places an undue burden on the State agency to deny these farmers' markets and farmers a contract because they fail to meet the current established WIC vendor selection criteria. Any burden for denying the farmers' markets and farmers should be clearly addressed by the Federal regulations and not by the State agency.

USDA has taken steps in the Cost Containment Interim Rule to ensure that above 50% vendors are not participating in the program. It has also established requirements for the State agencies to develop peer groups to control food costs. The above clause allowing the consideration of farmers' markets and farmers seems contrary to the purpose of the interim rule since these vendors will provide only fruits and vegetables unlike other vendors in Missouri who must be full-service groceries.

Missouri recommends clarifying the intent of Farmers' Markets in (E)(4)(c) to allow only States that administer a current WIC Farmers' Market Nutrition Program (WIC FMNP) the option to contract with farmers with permanent sites to redeem WIC cash vouchers for fresh fruits and vegetables. States that do not currently administer the WIC FMNP should not be allowed nor required to comply with this provision.

Missouri WIC recognizes that implementing the proposed rule will require excellent planning and thorough communication. There is great excitement and anticipation in Missouri's WIC Program regarding the promulgation of a final rule revising the WIC food packages. We are looking forward to fully implementing the proposed rule. We recommend that USDA partner with State agencies and the National WIC Association to assure a reasonable and flexible implementation timeframe of up to two years from the date of publication of the final rule.

Again, Missouri supports the proposed rule. We are convinced that it will serve to minimize vendor stock requirements, reduce the administrative burden on States and local agencies, *support* participant choice, and most important, focus attention on chronic disease prevention and control.

The proposed food packages will provide greater amounts of all of the priority nutrients currently identified as needed by the WIC population. They will supply a reliable and culturally acceptable source of supplemental nutritious foods as well as promote and support exclusive breastfeeding. Equally important, the proposals will provide WIC professionals with the necessary tools to reinforce the nutrition education messages and promote healthier food choices.

WIC is our nation's premier public health nutrition program. The long-term benefits of providing participants with fruits and vegetables, lower fat dairy products and whole grains, as well as additional incentives for fully breastfeeding women will greatly aid WIC in improving the life-long health of our most vulnerable women, infants and children.

We look forward to working closely with USDA to fully implement the proposed rule and urge finalization of the rule by no later than the spring of 2007.

Sincerely,

Lyn C. Konstant, Ph.D., R.D.
Missouri WIC Director



GSA-41

11-02-06 email from peggy.trouba@hhss.ne.gov

November 2, 2006

Patricia N. Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
USDA
3101 Park Center Drive
Room 528
Alexandria, VA 22302

RE: "Docket ID Number 0584-AD77, WIC Food Package Rule"

Dear Ms. Daniels:

Thank you for the opportunity to comment on the USDA's proposed WIC Food Package Rule, as published in the Federal Register on August 7, 2006.

The Nebraska WIC Program supports the Food Package Rule and the revisions that provide more healthy choices for women, infants, and children. The changes are in line with the 2005 Dietary Guidelines for Americans, recommendations by the American Academy of Pediatrics and reflects recommendations made by the Institute of Medicine (IOM) of the National Academies in its report, "WIC Food Packages: Time for a Change." They are based on current scientific information; they address emerging public health issues, such as obesity; they accommodate a variety of cultural food preferences and provide more support of breastfeeding.

We would like to offer the following comments:

- We support the addition of fruits and vegetables to the food package. This addition is consistent with requests from WIC participants seen in our Nebraska WIC participant Customer Survey. We strongly urge flexibility for WIC State Agencies in choosing the form in which fruits and vegetables will be provided. We support the addition of infant food fruits and vegetables and the elimination of juice from infant food packages. We strongly recommend that the dollar denomination of the fruit and vegetable cash-value vouchers and the minimum vendor stocking requirements for fruits and vegetables be determined at the discretion of the WIC State agencies.
- We would recommend that states be given the option to allow white potatoes as an acceptable fresh vegetable. White potatoes are the only vegetable excluded; this single exclusion could cause confusion for WIC participants and WIC vendors. This vegetable provides a source of Vitamin C, potassium, and fiber in the diet and is low in cost. Through nutrition education efforts at our WIC clinics, we would encourage low fat methods of preparation for this vegetable.
- We support the provision of soy-based beverages for participants who do not accept or tolerate cow's milk. We do request that those participants be allowed to receive soy-

based beverages without the proposed requirement of medical documentation, which is burdensome to participants, medical personnel, and staff.

- The proposed rule allows the state agency to authorize farmers at farmers' markets to accept the WIC cash-value food instrument for fruits and vegetables. We suggest the

Patricia N. Daniels

November 2, 2006

Page 2

rule be revised to allow only state agencies operating the WIC Farmers Market Nutrition Program the option of authorizing farmers at farmers' markets to accept WIC cash-value food instruments. Authorizing farmers markets outside of the FMNP would create an administrative burden on state agencies not operating the FMNP by increasing administrative time required to authorize additional vendors. Implementation of some of the vendor authorization requirements and the cost containment requirements would be difficult, specifically, requirements for: 1) minimum variety and quantity of supplements foods--states requiring all vendors to meet a requirement for stocking a variety of all types of foods; 2) competitive price criteria and peer groupings; 3) meeting the above 50% criterion--states would need to collect and review additional information from farmers markets to implement this criteria.

- Please consider the special needs of infants who need human milk fortifier until breastfeeding is fully established in the first month of life. These infants would be categorized as fully formula fed infants and could result in inaccurate breastfeeding statistics.
- We recommend states be allowed a longer implementation period for the rule than one year. A period of up to three years would be recommended. The rule impacts many areas of program operations from design of food packages to bank processing. Implementation of the changes will necessitate modifications to the computer system, program staff education, client education and focus, retailer selection criteria, retailer agreements, retailer training programs, food delivery system, and banking contracts. Sufficient time needs to be given to states so that changes can be coordinated at all levels of the program to achieve an effective and efficient implementation of the rule. For example: It would be recommended that changes be made to current systems as systems are modified and/or contracts renewed. This would provide for a more cost effective implementation plan.
- In order to accommodate the medical needs of certain participants, we urge the Department to include a provision in the final rule for State Agencies to include gluten-free cereal options.
- The proposed methodology for rounding of formula is complicated, creates confusion for participants and staff regarding the number of cans of formula participants will receive each month. We suggest the current method of rounding provided in the federal regulations be retained in place of the proposed methodology. We also suggest the current method of rounding be applied to all formulas issued including non-contract and exempt formulas, at the option of State Agencies.

We look forward to working closely with USDA to fully implement the proposed rule and urge timely finalization. Again, we strongly encourage state flexibility in implementation of the rule and in as many areas as possible.

Sincerely,

Peggy Trouba
Nebraska WIC Director

11-03-06 email from Evelyn C. Arnold, RD, LDN
Public Health Nutrition Consultant
Pennsylvania WIC Program
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earnold@state.pa.us



GSA-42

(717) 783-1289

October 27, 2006

Patricia N. Daniels
Director
Supplemental Food Programs Division
Food and Nutrition Service, USDA
3101 Park Center Drive, Room 528
Alexandria, Virginia 22302

Dear Ms. Daniels:

Please find attached comments from the Pennsylvania WIC State Agency regarding "Docket ID Number 0584-AD77, WIC Food Packages Rule." In general, we would like to lend our support for the proposed changes. It is an exciting prospect for WIC to make such changes in the foods we offer, and many of the proposed changes will better support the nutrition and health messages we incorporate into our daily contacts with participants.

Note that we have formatted our comments in such a manner as to state the proposed change, and our corresponding comments. Should you have any questions regarding our submission, please contact Shirley Sword of my staff. Thank you.

Sincerely,

Frank C. Maisano
Director
Division of Women, Infants and Children (WIC)



Proposed Rule – WIC Food Package Revision
Published August 7, 2006
Pennsylvania WIC Comments

INFANTS:

1. **Proposed Change:** During the first month after birth, infants will be categorized as either “fully breastfeeding” or “fully formula feeding.” No formula will be provided to any infant classified as breastfeeding during the first month. (There will be no “partially breastfed infants” during the first month).

PA Comment: Although we recognize that the intention of this proposed rule is to increase breastfeeding duration by preventing early formula supplementation, it raises the following concerns:

- It will likely decrease both incidence and duration because:
 - 1) Making formula unavailable on the breastfed package will motivate new mothers to request that their infants be changed to fully formula fed. Fear of inadequate milk supply is a common barrier to breastfeeding. Mothers want formula as a safety net and will ask their status be changed. Although the proposal suggests that this fear can be alleviated through lactation counseling, in reality, this often is not the case.
 - 2) It creates a negative perception. Benefits get ‘taken away’ if a woman chooses to breastfeed. (The provision of complementary foods at 6 months e.g., baby meats, etc. will not serve as an incentive for a prenatal woman or the mother of a newborn to breastfeed, especially when they perceive formula as a valuable program benefit.)
- It does not address the special needs of infants who need human milk fortifier or a premature/supplemental formula until breastfeeding is well established. (The proposal to give the mother the option to have her infant assigned as fully formula fed is inadequate because it not only allows breastfed infants to receive formula but technically permits them to receive a full package.)
- It can result in inaccurate breastfeeding statistics. A partially breastfed infant may be categorized as a fully formula fed infant in order to receive supplemental formula.
- It is unsupportive to the breastfeeding mother since her partially breastfed infant must be categorized as fully formula fed if she needs supplemental formula during the first month.
- It creates an administrative burden because breastfeeding women may request to switch their infants to full formula feeding and then switch back to fully or partially breastfeeding once the infant is one month old.

The NWA Breastfeeding Committee proposes that states be allowed the option of providing one can of formula if needed. However, we feel that this proposal does not go far enough to resolve the concerns stated above. Therefore, we suggest delaying formula for all infants until one month of age (unless there is a documented medical need for human milk fortifier or a special formula). Delaying infant formulas on all infants with the exception noted above will serve as an incentive for women to at least try breastfeeding and help prevent early supplementation without jeopardizing the health of infants with

special needs. Since standard formula is readily available during the first month from many non-WIC sources (free samples from doctor's offices, hospital discharge packets and formula company mailings and "baby clubs"), we suggest that the WIC Program take a stronger stand to promote and support breastfeeding.

2. **Proposed Change:** Beginning in the second month after birth, infants can also be considered "partially breastfed." A partially breastfed infant will be defined as a breastfed infant who receives up to about ½ the amount of formula allowed for a fully formula fed infant.

PA Comment: We support this limitation of formula because it will:

- Encourage breastfeeding by decreasing supplemental formula use.
- Give a clearer indication of mothers that are truly breastfeeding
- Decrease potential for fraud where mothers get a full food package and their infants get a full formula package

3. **Proposed Change:** The maximum monthly amount of powdered infant formula will be based on reconstituted fluid ounces when prepared according to the directions on the can, rather than pounds of dry powder.

PA Comment: This will provide more consistency in the amount of formula provided to all fully formula fed participants. Participants will be able to get more of expensive special formulas such as Elecare and Neocate which reconstitute to a lower yield than other formulas. This will be a great benefit to participants who do not have insurance/Medicaid coverage for these costly formulas. However, this will add substantially to WIC food costs and also add some initial administrative time and costs so data systems can incorporate the different yields of each type of formula.

4. **Proposed Change:** The maximum amount of formula for fully formula fed infants and partially breastfed infants will increase at 4 - 5 months and then decrease at 6 - 11 months.

PA Comment: Changing the amounts of formula for just month 4 and 5 will be cumbersome and confusing to both participants and staff. Since WIC is a supplemental program, we do not necessarily need to increase the amount of formula at month 4 and 5 to accommodate increased intake. Also, WIC may be able to encourage breastfeeding by letting pregnant women know that WIC will not provide all the formula that they need.

Instead, we suggest a smaller decrease in the amount of formula provided from 6 – 11 months (e.g. Instead of providing 24 cans of concentrate during the 6 – 11 month period as proposed, provide 28 cans/ month (about 23 oz/day). States should have the discretion to offer participants with special needs who do not take solids slightly more formula during month 6 through 11.

5. **Proposed Change:** Low iron infant formula will not be allowed for any infant.

PA Comment: We support this change as AAP does not recommend low iron formula for any

infant. Pennsylvania WIC currently does not provide low iron formula.

6. **Proposed Change:** States will have the option to amend their next formula contract to “round up” to the next whole can of powdered **standard infant formula** so the participant will get the full amount of reconstituted formula allowed over the infant certification.

PA Comment: The proposed rounding formula is much too complicated, and may be confusing for participants and staff as participants will get a different number of cans each month. *We agree with the NWA recommendation that USDA develop an alternative rounding formula that will allow for consistency in the number of cans of formula provided*

7. **Proposed Change:** Complementary foods (cereal, etc) will not be provided until 6 months.

PA Comment: We support this change to encourage delay of introduction of solids until most infants are developmentally ready.

8. **Proposed Change:** Juice will no longer be provided to infants. Instead, infants will be provided with jarred baby fruits and vegetables.

PA Comment: We support this change as it encourages timely introduction of solids and discourages excess juice.

9. **Proposed Change:** Fully breastfed infants will receive baby food meat.

PA Comment: We support this change which will provide breastfed infants with additional iron and zinc, and help encourage “full” breastfeeding with provision of additional foods.

CHILDREN AND WOMEN:

1. **Proposed Change:** Women pregnant with multiple fetuses and women partially breastfeeding multiple infants will be eligible for the same amount of foods as fully breastfeeding women. Women fully breastfeeding multiple infants will be eligible for 1.5 times the amounts of foods as other fully breastfeeding women.

PA Comment: We support this change if WIC has the funds to accommodate it.

2. **Proposed Change:** A partially breastfeeding woman who requests more than the maximum amount of formula for a partially breastfed infant after the 6th month post-partum would no longer receive a food package but would continue to count as a WIC participant and receive other Program benefits.

PA Comment: Participation counts are currently based on food package redemption. Since this proposal permits women who do not receive a food package to be counted as a WIC participant, it will necessitate a change in current requirements regarding participation counts. How will this be addressed? Currently, only purely breastfed infants (those not receiving any WIC benefits) are being included in participation counts as a special situation.

Categorizing the infant as fully formula fed and the mother as breastfeeding will create confusion regarding the very definition of breastfeeding. Who will get counted in WIC breastfeeding statistics, the mother or the infant?

The health benefits of token breastfeeding (such as breastfeeding on an average of once per day) are minimal. Healthy People 2010 goals include a goal of exclusive breastfeeding and there is a need to pursue this objective. If 'token' breastfeeding women are counted as WIC participants, we suggest that they not be included in breastfeeding statistics unless extent of breastfeeding is also clarified.

Ideally, we would prefer to see USDA adopt the IOM's proposed definition for breastfeeding, and follow the IOM's recommendation to discontinue certification for a partially breastfeeding mother who requests more than the maximum amount of formula for a partially breastfed infant. The current calculation of breastfeeding rate $(B/B+N) \times 100$, is not truly a reflection of breastfeeding rates in a state, and may stand to decrease if this definition is adopted. However, a truer picture of the extent of breastfeeding within a state could be achieved by capturing the data of infants who are being breastfed rather than that of mothers.

Milk and Milk Substitutes:

3. **Proposed Change:** Only whole milk will be allowed for children 12 – 23 months. Only 2% or less milk will be allowed for participants ≥ 24 months.

PA Comment: In general we support this recommendation, but feel that the nutritionist should have the option to work with the physician to tailor the type of milk when nutritionally appropriate (e.g. provide whole milk for a very underweight child over age 2 or provide 2% milk for a very overweight child under age two who is eating other high fat foods)

4. **Proposed Change:** Milk and alternatives will decrease:

Participant Type	Current Max	Proposed Max
Children and Postpartum Women	12 Half Gal / month	8 Half Gal/ Month (2.1 cups/day)
Pregnant and Partially Breastfeeding Women	14 Half Gal /month	11 Half Gal/ Month (2.9 Cups/day)
Fully Breastfeeding Women	14 Half Gal/month	12 Half Gal/ month (3 2 cups/day)

PA Comment: We support this change, as it allows us to provide other foods and helps us to discourage excess milk consumption.

5. **Proposed Change:** Cheese will be limited to 2 lb/month for Fully Breastfeeding women and 1 lb/month for other women and children. Limits can be exceeded with prescription with documentation of lactose intolerance or other qualifying condition.

PA Comment: We feel that limitation of cheese should be a recommendation rather than a rule. Many women and children eat cheese as an alternative if they do not like or tolerate a lot of milk. Requiring a prescription to override the limit is an unnecessary administrative burden. Many physicians do not like to spend time writing prescriptions, even for formula, and some have asked to be paid for the cost of completing WIC prescriptions and forms. If limits to cheese must be set, we suggest more lenient limits of 4 lbs cheese for fully breastfeeding women and 2 lbs of cheese for all other categories.

6. **Proposed Change:** Calcium set tofu will be added. A prescription will be required to provide any amount tofu to children

PA Comment: We support states having the option to allow tofu as an alternative for clients who do not accept or tolerate milk. However, many smaller stores in Pennsylvania do not carry tofu and it may be a burden for them to do so because it may not sell in their area. Calcium set tofu (vs. tofu that is not calcium set) will be difficult for cashiers to identify by reading the label, so food lists would have to specify exact brands allowed, further limiting choices.

We request that a prescription not be required for tofu, as it would be an unnecessary administrative burden for staff and physicians as described in #5 above.

7. **Proposed Change:** Soy based beverage "Soy Milk" will be provided. Must contain specified minimum amounts of Calcium, Protein, Vitamin A, Vitamin D, Magnesium, Phosphorus, Potassium, Riboflavin and B 12. A prescription will be required to provide any amount of soy milk to children.

PA Comment: We enthusiastically support the provision soy milk to participants who do not accept or tolerate cow's milk. Each year, we receive many requests from participants for soy milk. NWA indicates that there are currently no soy beverages on the market that meet the nutrient standards in the proposed regulations. However, the IOM was specific in its recommendation that "*Soy beverage must be fortified to contain nutrients in amounts similar to cow's milk.*" It would be ideal if the industry would respond to the criteria WIC is proposing for protein, potassium and calcium content of soy beverages, rather than for WIC to reduce its requirements for key nutrients. A compromise may be inevitable. We also request that a prescription not be required for this product for the reasons noted in #5 and 6 above.

Eggs:

8. **Proposed Change:** Maximum amount of eggs will decrease to 1 dozen for children, pregnant, partially breastfeeding, and postpartum women and to 2 dozen for fully breastfeeding women.

PA Comment: We support this change as it will allow for provision of other foods

Beans and Peanut Butter:

9. **Proposed Change:** Pregnant and Partially Breastfeeding Women will be allowed peanut butter AND beans (Currently they are only allowed peanut butter OR beans). Postpartum women will be allowed a choice of peanut butter OR beans. (Currently they are allowed neither).

PA Comment: We support this change as it will provide increased nutrients and fiber for these women.

10. **Proposed Change:** Canned beans will be an allowable substitute for dry beans and peas.

PA Comment: We enthusiastically support this change as it will encourage the use of beans.

11. **Proposed Change:** Reduced fat peanut butter will be allowed if it meets the FDA standard of identity for peanut butter.

PA Comment: Most name brands of reduced fat peanut butters are “peanut butter spreads” and will not meet WIC criteria.

Juice, Fruits and Vegetables:

12. **Proposed Change:** Juice will be decreased to less than ½ the current allowable amounts.

PA Comment: We support this change as it will discourage excess juice consumption that can contribute to overweight and/or poor appetite for solid foods.

13. **Proposed Change:** Children will receive a \$6 cash voucher and women will receive an \$8 cash voucher for any combination of fresh, canned, or frozen fruits and vegetables.

PA Comment: We support this change as it will enhance our nutrition education efforts to promote fruits and vegetables. *We agree with NWA's recommendation to increase the amount of the voucher to \$10 for fully breastfeeding women only, as an additional incentive for fully breastfeeding women (if budget allows). We also support NWA's recommendation for states to be able to decide the denomination of the voucher.*

NWA also recommends and PA supports allowing states to use existing Farmer's market vendor certifications (rather than having the Farmer's market meet vendor requirements which would be impractical) as an option for redemption of fruit and vegetable vouchers.

Breakfast Cereals and Other Whole Grains:

14. **Proposed Change:** All WIC cereals for women and children (“Breakfast Cereals”) will meet the labeling requirement for “whole grain food with moderate fat content” or be 51% whole grain.

PA Comment: This option would eliminate corn and rice based cereals and most hot cereals except oatmeal. These cereals may be needed for some clients with allergies, gluten

intolerance (although there are very few corn and rice based cereals that are totally wheat or gluten free), or other medical conditions. Most of the low-phenylalanine cereals used by PKU participants would also be eliminated. *We do not feel the NWA suggestion to allow "wheat free" cereal only for participants with certain medical diagnoses would be logistically feasible at the vendor level. It would be difficult and awkward for vendors to have to identify certain types of cereals for only certain clients. Many vendors program the allowable cereals into their cash registers, making exceptions is cumbersome.*

We therefore suggest "8 gm whole grain" as the criteria which would allow some corn, rice, oat, and wheat cereals. This would still provide clients with whole grain, and the following cereals, which would no longer be allowed under the 51% whole grain rule, would be allowed: Kix, Country Corn Flakes, Corn Chex, Rice Chex, Multigrain Chex, Dora the Explorer, Honey Bunches of Oats.

15. **Proposed Change:** Children and Pregnant and Breastfeeding women will be provided whole wheat bread or other whole grain options (at State Agency discretion).
- Bread must conform to FDA standard of identity for whole wheat bread OR must meet labeling requirements for whole grain food with moderate fat content.
 - Allowable substitutes for whole wheat bread include:
 - Brown rice, bulgur, oatmeal, whole grain barley without added sugars, fats, oils, or salt.
 - Soft corn or whole wheat tortillas without added fats or oils

PA Comment: While we are aware of the nutritional benefits of providing whole wheat bread and other whole grains, we are concerned about the logistics of implementing this change, particularly at the WIC vendor level:

- Whole wheat breads may be difficult to distinguish from "Wheat Breads", which will not be WIC allowable.
- Labeling claims are confusing, and still not well regulated. Examples of labeling claims include: "Good Source of Whole Grain," "Excellent Source of Whole Grain," "8 Grams of Whole Grain." Although some of these claims are not allowed according to FDA regulations, they are still used.
- The proposed rule allows for 1 lb of whole wheat bread for some participant categories. Whole grain bread is not generally packaged in 1 lb or less packages.

We support the addition of whole wheat bread and other whole grains only if:

- the above logistic concerns are addressed
- State agencies truly have the option to only include items that are readily available and administratively feasible in their state.

Canned Fish:

16. **Proposed Change:** Canned salmon and sardines packed in water or oil will be allowed as substitutes for light canned tuna for fully breastfeeding women.

PA Comment: We support this change.

PARTICIPANTS WITH QUALIFYING CONDITIONS (Infants, children, and women)

1. **Proposed Change:** Participants must have medical documentation (prescription) verifying a *qualifying medical condition* to receive special formula.
 - The *qualifying conditions* include but are not limited to prematurity, low birth weight, failure to thrive, metabolic disorders, GI disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption, and utilization of nutrients that could adversely affect the nutritional status.

PA Comment/Question: We have often run into situations where failure to thrive (FTT) is used as the medical diagnosis, but our growth charts do not provide the support to justify this diagnosis. It puts WIC staff in a position of questioning a physician's diagnosis, which can be very intimidating. Overuse of some special formulas such as Pediasure, Nutren Jr., and Kindercal in healthy children who are picky eaters yet diagnosed with FTT can deter the development of good eating habits and negatively impact food costs. Can the rule be strengthened (e.g., by allowing states to set growth parameter criteria for a diagnosis of FTT) to support WIC in its efforts to insure that these special formulas are utilized appropriately?

2. **Proposed Change:** Infants, Children, and Women *with the above qualifying medical conditions* who receive formula from WIC will also be able to get maximum amounts of other WIC foods appropriate for their life stage (e.g. milk, fruits and vegetables, beans, etc.) with medical documentation that the foods are not medically contraindicated for their special needs. Currently participants who receive formula from WIC can only get formula, juice, and cereal.

PA Comment: We support this change as it encourages increased use of solid foods when appropriate for participants with special needs, but wonder if the complete food package should be given only when a participant receives less than or equal to half of the maximum amount of formula. If the formula need is greater, decrease the food package allotment by half to decrease the potential for fraud or shared use of foods in a household.

3. **Proposed Change:** Infants will not be able to receive special formulas designed for children and adults (Medical Foods).

PA Comment: Some infants with qualifying conditions have a medical need for Medical Foods designed for children. WIC should be allowed to provide these medical foods to such infants when they are consuming them under medical supervision.

4. **Proposed Change:** Some new medical foods in the form of gels, capsules, bars (e.g. for PKU) and RTF puddings will be WIC eligible.

PA Comment: We support this change.

5. **Proposed Change:** In addition to the current allowable reasons for RTF formula (unsanitary or restricted water supply or inability to prepare conc or powder, formula only available in RTF), *participants with Qualifying Medical Conditions* will also be able to receive RTF formula for the following reasons:

- The RTF form better accommodates the participant's medical condition
 1. RTF semisolids such as bars for someone with a swallowing problem
 2. RTF reduces the possibility of contamination and risk of infection for participants with immune system disorders.
- RTF improves compliance in consuming the prescribed formula (e.g. RTF bars taste better than RTF liquid)

PA Comment: We support this change as it allows RTF in circumstances that will benefit the health and nutrition status of special needs participants.

6. **Proposed Change:** Participants with qualifying conditions will be able to receive 32 oz dry infant cereal as a substitute for 36 oz adult breakfast cereal when justification is documented by CPA or medical provider.

PA Comment: We support this change.

Other:

Proposed Change: WIC will be required to provide the maximum allowable food package to each participant unless the CPA determines that lesser amounts are medically or nutritionally appropriate (e.g. allergies), the participant cannot use/refuses the foods, or needs are being met by another program. Individualized food package tailoring would continue to be encouraged, but food packages could not be reduced for cost savings, administrative convenience, caseload management, or to control vendor abuse.

PA Comment: In the current environment of our data system, the maximum allowed for each food package is always available, but PA had adopted a series of model food packages that provided juice and milk in quantities that followed the recommendations of AAP and the dietary guidelines. Staff would tailor quantities up to the maximum allowed for all WIC types, rather than to start at the maximum allowed and tailor down. From a health perspective, it made more sense for us to do it that way. The new rule will propose maximum quantities for juice and milk that are in alignment with the current amounts in our model food packages, but, in general, the new food package options will require a considerable amount more tailoring than in the past. Staff will need additional training tools to help facilitate the tailoring of packages in a busy clinic setting, particularly in situations where there are not sophisticated data systems that have the capability of calculating allowable substitution rates automatically.

Proposed Implementation Timeframe: The Proposed Rule suggests a 6 month implementation timeframe for juice elimination for infants and a one year implementation timeframe for most other parts of the rule.

PA Comment: Although we recognize the benefits to participants of many of the proposed

changes, we feel the timeframe is too short and suggest that USDA carefully consider provision of a more realistic implementation period for the following reasons:

- Each State will have to update their Food Card (Food List). Manufacturers will need to submit applications for the new products (many of the new foods will need to be brand specific on the list) and resubmit current products such as cereals to make sure they meet new specifications. Review of new items, production and printing of a new food card can take up to 5 - 6 months for a large state.
- WIC staff will need to be trained about the criteria for the new food items and food packages, and then learn how to appropriately and accurately tailor food packages.
- Vendors will need to be trained on the substantial changes, particularly the use of the new "cash value" voucher for fruits and vegetables, and the new allowable WIC foods. Pennsylvania has approximately 1500 vendors that will require this training. The bulk of this responsibility will fall on local agency staff, and then stores will have to train and prepare all their staff.
- WIC participants will need to be informed about their new options. This will require additional time for appointments, resulting in fewer participants being seen on a daily basis.
- Infant juice, which will be eliminated, is a part of required minimum inventory for vendors. Many small vendors only stock these items because of WIC, and will need ample notice to decrease their stock. The need to provide a greater variety of foods may also result in difficulties in authorizing smaller stores who are limited in the amount of inventory they can manage. Some states may need to promulgate state regulations to accommodate changes in the foods and quantities required by vendors.
- Many states have contracts for infant juice and cereal which may need to be amended because of the elimination of infant juice. The addition of baby fruits, vegetables, and meat may require contract amendments and/or vendor regulations.
- Data systems will need major updates and enhancements to accommodate the inclusion of new foods, changes in the calculation of powder formula provided based on reconstituted yield, and more complicated verifications of food package rules. WIC check forms will also need to be updated to accommodate additional character spaces

GSA-43

From: wblackmon@adph.state.al.us
Sent: Friday, November 03, 2006 1:04 PM
To: WICHQ-SFPD
Cc: CarolynBattle@adph.state.al.us; Monahan, Jane; chaag@adph.state.al.us
Subject: Docket ID Number 0584-AD77, WIC Food Packages Rule

November 2, 2006

Patricia N. Daniels, Director
Supplemental Food Programs Division
Food and Nutrition Service, USDA
Room 528
3101 Park Center Drive
Alexandria, VA 22302

Dear Ms. Daniels:

Thank you for the opportunity to comment on the proposed changes to the WIC food package. We appreciate the complex details that were addressed in developing these much needed enhancements to the benefits of our WIC patients.

We are overwhelmingly in favor of the changes and will work with USDA to implement these over a period of time to achieve the most effective transition for our patients, clinic staff, grocers and other stakeholders.

The following are our comments and suggestions on the proposed rule:

We think the three feeding options are viable; however, education for staff, patients and many hours of computer programming will be necessary. The exclusively breastfed food package will increase the incentive to initiate and possibly increase the duration of breastfeeding with the quality and quantity of foods offered. The number of jars provided may require two or more food instruments for the infant and will require more shelf space by grocers to accommodate the additional foods. Overall, this will be well accepted by our patients and staff to promote breastfeeding. The infant food package has achieved the recommended delay of introduction of solid foods until six months of age. We agree with not providing juice to infants and giving different maximum amounts in children and women food packages. The challenge for the infant feeding options will be programming and determining the foods offered if the pickup date is between the age cut-offs outlined in the guidance. For the partially breastfed infant, we endorse the reduction of the maximum amount of formula that may be given. Please reconsider giving these mothers food instruments after six months. We feel this may be a disincentive to the continuation of breastfeeding because we have many mothers whose worksite will not allow them to

pump. We prefer to give these mothers a reduced food package and let them continue if they breastfeed at least once a day as currently provided by regulation.

We are concerned that giving fruits, vegetables and meats at the same time to infants contradicts the nutrition education concerning the introduction of solids. We would recommend that you allow states the option of not giving bananas due to spoilage and the demands that some customers place on stores to get exactly one pound of product.

We approve of the change to express monthly maximums in reconstituted fluid ounces. We are puzzled as to why the exempt formulas are not included in rounding up.

We are fully behind the addition of fruits and vegetables; however the delivery and food packaging needs to be re-evaluated. Additional costs of printing and processing \$6.00 and \$8.00 coupons would not be a good use of tax dollars. We recommend that USDA allow states to add these to the current food instrument system and provide the flexibility of which form (frozen, canned or fresh) states may use. If allowed to do so, we would add pound size bags of frozen fruits and vegetables. Frozen produce allow participants to fix only the amount needed at the time of consumption; most are reasonably priced; have a lower sodium content than canned (vegetables); are convenient for participants since most require little preparation time; eliminate store disputes if the exact weight of fresh produce does not exactly equal the dollar amount; and are available year round with no spoilage. Offering frozen fruits and vegetables also does not interfere with the WIC Farmer's Market Nutrition Programs operated in many states; participants may prefer their locally grown, seasonal offerings at the markets or farmer's stands.

We recommend the elimination of the medical documentation for soy-based beverages and for additional cheese or tofu. The physicians would not understand this burdensome requirement.

We fully support the addition of salmon and sardines to the food package; offering whole milk only to the one year to 23 month old children and 2% or less milk to women and children 2 years and older; and the 1.5 times quantities for fully breastfed and multiple fetus or births.

Some questions we had were:

Is Carnation Instant Breakfast drink approved under these proposed rules?

For Food Package 3, what would we do if the mom is exclusively breastfeeding and needs human milk fortifier?

Although it is requested on page 44804, we have no experience to comment on the equivalents of the maximum amounts monthly. We recommend consultation with hospitals or universities.

While we support the disallowance of low iron formulas as a standard practice, we are concerned that there may be medical diagnoses that would warrant the issuance of low iron formula such as in the case of hemochromatosis. The proposed rule does not allow

for issuance of low iron formula under any circumstance. Would any exceptions be allowed?

We anticipate a great deal of education will be needed for our repeat WIC customers, grocers, physicians and staff, especially regarding the partially breastfed infant option. Approximately 90% of our infant pamphlets will need revision. Development of materials, putting out bids on printing, the actual printing, and the programming and testing of computer revisions will take longer than one year from publication of the interim rule. We have manual food instruments that are used in times of disasters which will have to be developed and printed. We also anticipate more banking costs due to increased number of food instruments. Please consider a longer implementation period or a phase in of the different food packages over a period of time so that this is more acceptable to all impacted. Since we are a part of the Crossroads Consortium (SAM), we are also in a predicament of exactly what food items would need to be included in the food packages and the associated costs that would have to be borne by changes in programming.

Again, thank you for these long awaited and direly needed enhancements to the WIC food package. Please contact Carolyn Battle, Alabama WIC Program's Nutrition Director, or me at (334) 206-5673 if you have any questions regarding these comments.

Wendy S. Blackmon, Director
Division of WIC
Bureau of Family Health Services
Alabama Department of Public Health

GSA-45

From: Donna T Seward [Donna.Seward@vdh.virginia.gov]
Sent: Friday, November 03, 2006 11:08 AM
To: WICHQ-SFPD
Subject: Docket ID Number 0584--AD77, WIC Food Package Rule

Attachments: COMMONWEALTH of VIRGINIA.doc; Card for Donna T Seward
<Donna.Seward@vdh.virginia.gov>

Comments for the Commonwealth of Virginia WIC Program are attached.

Donna T. Seward, CHE
Director, Division of WIC & Community Nutrition Services Virginia Department Of
Health



COMMONWEALTH of VIRGINIA

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November 3, 2006

As Director of the Virginia WIC Program with more than thirty years experience in WIC, I want to commend USDA FNS both for asking IOM to evaluate the WIC food package and for moving to implement their recommendations. These much needed changes will make the program consistent with current nutrition and science and practice and will allow the program to be more responsive to its diverse populations.

While it is Virginia's intent to comment on much of the proposed rule, and specifically respond to those areas where you have requested input, we want to first register three main concerns:

- In order to continue our strong efforts toward cost containment while meeting the nutritional needs of Virginia WIC clients, it will be critical that states have maximum flexibility, particularly in areas of limitation and vendor requirements, relative to these rules. While the current proposed rule appears to do that in most

cases, the appearance stems from lack of restrictions rather than any clear declaration of state discretion.

- We have waited many years for changes in the food packages, and the WIC community is eager to implement a new food package rule. However, the one year timeline for implementation is unrealistic. Not only will states need to research needs and preferences of their participants as well as availability of foods and forms, but significant changes will also be required in MIS systems. Some of the changes will be easy to implement, while others will add significant new complexity. In addition, such massive change will require significant educational efforts toward both staff and participants. It seems imprudent to move hastily in implementing changes long awaited. We would propose that these changes be handled more like the recent vendor regulations and even VENA, in that each state should be allowed/required to submit a plan for implementation based on the automated system, cost containment practices and ethnic/cultural requirements of their individual state.
- Our third and final major concern is our strong objection to the perpetuation of the myth that infants need commercial baby food. This is totally inconsistent with the general support of good consumerism so integral to the WIC Program. The WIC community has been encouraging and supporting mothers to make their own baby food for years, and a change to providing jar foods would not only damage their credibility but send the wrong message to mothers in general.



Food Packages I and II for Infants

We believe that the distinction of three feeding options supported by specific food packages is needed in the program. There is a great deal of difference between the mother who breastfeeds all but once a day, and the one who only breastfeeds once a day. We concur with the distinction being made at the halfway mark on formula provided. As we believe that the program needs to support its own education by providing fruits and vegetables to infants. **We do not feel that it is necessary or prudent to provide fruits and vegetables in the form of commercial baby food.** We strongly support the elimination of juice in both packages. In addition, we believe that restricting formula in the first month of life is acceptable, as long as it is paired with good support for the breastfeeding mother. While meat for breastfed infants is supported, the quantity proposed is somewhat excessive. We caution the department against assuming that powder is the most economical form of infant formula for states. This is not true in all states based on the specifics of their rebate contract. We support the reference to ounces of reconstituted infant formula for all forms. The clarification regarding infant cereal will support our current state policy. **While we support substitution of fresh bananas for commercial baby food, it does not go far enough in that states should have the option not to provide commercial food at all.** We believe that referencing ounces of reconstituted formula will assist states in dealing with packaging issues among formula

products. The rounding methodology in the regulations is far too complex for either client understanding or MIS support. States need to maintain their current discretion in choosing whether to round, and in the methodology of rounding. This is true of both formula and other infant foods. We believe that all changes in these food packages are feasible, but again **urge individual states to establish their plan for implementation.**

Food Package III Participants with Qualifying Conditions

We support the consistency derived from moving infants with special needs to food package III. We further support providing appropriate supplemental foods to these food packages when not medically contraindicated, with one stipulation: that exempt infant formula provided replaces milk products in the food package. We concur with the revised definition of medical foods. We believe that the inclusion of additional ready-to-feed medical foods will likely have serious negative cost impact on food packages. Likewise, the complexity of determining quantities of these foods will require significant MIS support. We have found in working with our Metabolic Treatment Centers in Virginia, that kilocalorie equivalent is the most consistent measurement across all products and recommend that for WIC purposes as well. We support the expansion of conditions under which ready-to-feed formula can be issues in this food package. In Virginia we have successfully negotiated with the Medicaid agency in our state for them to be primary payor for exempt infant formulas and medical foods. However, we are well aware of the barriers many state agencies are facing to move in this direction, and recommend that the department make a much stronger statement in the proposed rules to support these efforts.

Food Packages V, VI and VII

We strongly support the distinction of food packages for breastfeeding women based on the amount of formula provided their infant. We believe this will encourage more breastfeeding as well as support our educational efforts to encourage mothers to breastfeed more and supplement with breast milk instead of formula. We further support the allowance of both legumes and peanut butter for food package V. The addition of legumes or peanut butter to food package VI is a good one. We also support assigning pregnant women with multiple fetuses in utero to package VII. While we philosophically support increased amounts for women breastfeeding more than one infant, we find the proposed increase of 1.5 times the food in food package VII to be overly complex. We believe that it would be more appropriate to create a food package VIII for this purpose. We strongly support maintaining mothers who are partially breastfeeding after the sixth month postpartum period as participants for receipt of the non-food benefits of the program. This acknowledges the importance of these non-food benefits and will support mothers' breastfeeding to some extent for a longer period.

Fruits and Vegetables

We strongly support the addition of fresh, frozen or canned vegetables to the food packages III through VII. However, we do believe that the requirement that it be through cash-value food instruments is unnecessarily complex. We do, however, acknowledge the department's efforts to determine how to best implement this requirement. Having participated in WIC FMNP, we believe the same solution can be applied to this requirement. The true challenge with this requirement is ensuring that participants practice good consumerism and good nutrition in their purchases. We have serious doubts about the cost neutrality of these proposed rules, and concur with the department's reduction of the IOM proposed amounts. We would however, recommend that food package VII have the full \$10. We support the flexibility allowed to states as to the denomination of the cash-value food instruments. We support the department's restriction on white potatoes based on starch, but believe this should be broadened to include other starchy fruits and vegetables, especially corn.

Legumes and Peanut Butter Substitution

We support the IOM recommendation to allow canned legumes to substitute for dry legumes. However, we believe that the department's expansion on this to mix dry legumes, canned legumes and peanut butter in packages adds an unnecessary complexity and increased food costs. We would urge the department to limit the proposed rule to the IOM recommendations.

Whole Grains

We support the inclusion of whole grains, and are pleased to see specific FDA definitions for the products. We believe that authorizing bread and allowing substitutions may not be the most appropriate, particularly in light of the increasing obesity rates and lack of clear data supporting a shortage of bread in diets. We believe the authorized food should be grains themselves, with bread and tortillas as a substitute. That said, the rule can certainly be implemented in this way by the state. We are concerned about the limited availability of hot cereals with the required whole grain levels.

Milk and Milk Alternatives

The Virginia WIC Program has been issuing only whole milk for children one year of age and lowfat milk for all other ages and women. We have restricted cheese substitution to two pounds, but support the further restrictions recommended. We agree with inclusion of soy-based beverages as this has been a source of contention in our state for some time. We also support the reduction in monthly maximums for all participants. We do **not** agree with the requirement for medical documentation for issuance of soy milk and/or tofu to children. While we concur that a child's medical provider needs to be aware of these diet patterns, we believe there are a variety of far less onerous ways of assuring this than requiring medical documentation. These products are readily available in grocery stores. Requiring medical documentation places an increased administrative burden and cost on local agencies and does not foster a good relationship with the medical

community in this situation. In addition, while the higher requirements for protein and potassium in soy milk may be ideal, we believe it is illogical to mandate these standards when no product currently on the market can meet them.

Eggs

We support the reduction in allowable quantity of eggs.

Canned Fish

We support the authorization of both salmon and sardines in addition to tuna.

Juice

We support the reduction in allowable quantity of juice.

Medical Documentation

We believe that the information added as requirements for medical documentation represent minimum requirements already in place in many states. We support their inclusion. We strongly support the department acknowledging that it is not within WIC's responsibility for close medical supervision of participants with qualifying medical conditions. We agree that the WIC CPA must adhere to the health care providers' documented amounts.

Implementation of Revised Packages

We want to re-iterate our strong belief that a one year implementation timeframe is totally unrealistic and impractical. States will need to do significant research in order to determine which products and forms will be allowed in their state. In many states, this will require changes in state regulations. States will need to not only determine minimum stocking requirements for vendors, but notify them and allow a reasonable amount of time for them to come into compliance. For states providing three months issuance of food instruments, a minimum of fifteen months is necessary to implement any change. The changes required for the breastfeeding mother and infant dyad are no more complex than the others and do not warrant the long delay proposed. This change should be included in a state plan for implementation. A six month timeframe to eliminate juice is reasonable, but it will require more than one year to implement other changes in formula food packages. It will require more than one year for all of the background work to be done to implement these changes and states would not have any phase-in time with participants.

In analysis of the reporting and recordkeeping burden, the department fails to recognize the significant administrative burden for medical documentation requirements for soy milk and tofu for children. All medical documentation is time-consuming and complex,

but certainly acceptable in the case of qualifying conditions. These products will not be limited to qualifying conditions and should not be limited in this way.

Cost Neutrality

While acknowledging the administrative burden for states for each proposed change, it does not appear that the cumulative burden of implementing this many changes at once has been considered. It is not clear that the loss of rebate dollars resulting from the reduced amounts of infant formulas prescribed has been researched and considered. It further is not clear that the significant cost of providing other WIC foods in food package III has been adequately considered.

Again, we support the revision of the WIC food packages and support the categories of foods added. We further support the new limitations on quantity of some foods. We are eager to implement changes but are seriously concerned about the timeframes discussed. As always, we appreciate the department's willingness to receive comments and past responses to those comments.

Sincerely

Donna T. Seward, Director
Division of WIC and Community Nutrition Services

From: WebMaster@fns.usda.gov
Sent: Friday, November 03, 2006 6:18 PM
To: WICHQ-SFPD
Subject: RevisionstoWICFoodPackages-Proposed Rule

NAME: Betsy Clarke
EMAIL: betsy.clarke@health.state.mn.us
CITY: St. Paul
STATE: Minnesota
ORGANIZATION: MN Department of Health
CATEGORY: Other
OtherCategory: WIC Director
Date: November 03, 2006
Time: 06:17:36 PM

COMMENTS:

November 3, 2006

Patricia N. Daniels
Director, Supplemental Food Programs Division Food and Nutrition Service USDA
3101 Park Center Drive, Room 528
Alexandria, VA 22302

Docket ID Number: 0584-AD77-WIC Food Packages Rule

Dear Ms. Daniels:

I am writing to express Minnesota WIC Program support for the proposed food package rule change. The health and well-being of women, infants, and children is a priority of our organization. The proposed changes will greatly benefit vulnerable mothers and children.

We are pleased that the proposed rule closely reflects the science-based recommendations of the Institute of Medicine that were published in their April 2005 report entitled, WIC Food Packages: Time for a Change. The changes reflected in the proposed rule are also consistent with the 2005 Dietary Guidelines for Americans and national nutrition guidance including those from the American Academy of Pediatrics.

We agree that the changes in the proposed rule are a significant step forward and will improve the overall health of WIC mothers and children by contributing to reductions in obesity and other diet-related chronic diseases. In particular:

- We support adding fruits and vegetables to the food packages of women, infants and children while reducing the amount of fruit juice provided. Increased consumption of fruits and vegetables is associated with reduced risk for obesity and chronic diseases such as cancer, stroke, cardiovascular disease, and type 2 diabetes. Fruits and vegetables added to the diet also promote adequate intake of priority nutrients such as Vitamins A, C, folate, potassium and fiber.
- We support the quantities of dairy products and eggs offered in the proposed rule. These quantities meet the 2005 Dietary Guidelines for Americans. We agree that alternative calcium sources such as soy beverage (soy milk) and tofu are necessary additions to the food packages to address milk protein allergy, lactose maldigestion, personal preferences, and cultural diversity of the WIC population.
- We support the whole grain requirement for cereals and the introduction of whole grain bread and other whole grains such as corn tortillas and brown rice. Whole grain consumption is associated with 1). reducing the risk of coronary heart disease, type 2 diabetes, digestive system and hormone-related cancers, 2). assisting in maintaining a healthy weight, and 3). increasing the intake of dietary fiber.

We have these recommendations for final regulations:

- In regard to the proposed language on nutrition tailoring 246.10 c, we suggest that this language be eliminated. States should be able to reduce food amounts for groups, especially when organizations such as branches of the American Medical Association or a state Pediatric Association requests changes based on research. Additionally, states should not be forced to eliminate groups of certified participants from the program to balance the budget. In times of budget crisis, some WIC foods are better for children and women than no WIC foods. Don't force states to remove whole categories of participants when partial packages with continuing nutrition services would better serve the population during times of budget cuts.
- To further support breastfeeding, we urge that the cash-value vouchers for fruits and vegetables for fully breastfeeding women be increased to \$10. We believe that this change could be cost-neutral if states could make further reductions in juice amounts and would provide a significant incentive for breastfeeding mothers.
- While we commend USDA's efforts in the proposed rule to support the initiation and duration of breastfeeding, we urge that there be no test period for the partially breastfeeding food packages for women and infants. We believe that deletion of the pilot phase would speed the implementation of these packages. For women who declare themselves as breastfeeding moms, we urge that, consistent with the

IOM recommendation, states be given the option to establish criteria under which infant formula may be provided in the first month.

- Reconsider elimination of all canned fruits with sugar. While we all agree that fruit is best without sugar, the reality is that the vast majority of fruit is canned in sugar syrup. In very remote places with little availability of fresh fruit, it may be necessary to allow canned or frozen fruit with sugar in order to have fruit available at all. Add language to assure the availability of fruit in all areas.
- Due to the more complex nature of the food package, we recommend that USDA be responsible for developing and maintaining a comprehensive list of products eligible for the Program. A centralized list is more cost effective than having each state keep such a list.
- We are pleased with the addition of canned beans. We suggest that fat free or vegetarian refried beans should also be eligible items for purchase.

The Minnesota WIC Program commends USDA for the release of the proposed rule making major changes to the WIC food packages. This proposed rule makes the WIC food packages consistent with the 2005 Dietary Guidelines for Americans and is a major step forward to improve the overall nutritional health and well-being of WIC mothers and children.

The proposed food packages will provide greater amounts of all of the priority nutrients currently identified as needed by the WIC population. They will supply a reliable and culturally acceptable source of supplemental nutritious foods as well as promote and support exclusive breastfeeding. Equally important, the proposals will provide WIC professionals with the necessary tools to reinforce the nutrition education messages and promote healthier food choices.

WIC is our nation's premier public health nutrition program. The long-term benefits of providing participants with fruits and vegetables, lower fat dairy products and whole grains, as well as additional incentives for fully breastfeeding women will greatly aid WIC in improving the life-long health of our most vulnerable women, infants and children.

The Minnesota WIC Program urges publication of a final rule by the spring of 2007 to assure timely implementation of the changes.

Sincerely,

Betsy Clarke
MN WIC Director

From: WebMaster@fns.usda.gov
Sent: Monday, November 06, 2006 1:09 PM
To: WICHQ-SFPD
Subject: RevisionstoWICFoodPackages-Proposed Rule

NAME: Valerie Wolfe
EMAIL: valerie.wolfe@dshs.state.tx.us
CITY: Austin
STATE: Texas
ORGANIZATION: Texas Department of State Health Services , Nutrition Services
Section, WIC Program
CATEGORY: WICGeographicSA
OtherCategory:
Date: November 06, 2006
Time: 01:09:19 PM

COMMENTS:

Dear Ms. Daniels:

Thank you for the opportunity to provide comments on the USDA's proposed regulations that revise the WIC Food Packages published in the Federal Register August 7, 2006.

On behalf of the Texas Department of State Health Services and the 900,000 WIC participants we serve, we strongly support these long-awaited reforms that will provide the families we serve with healthier, more varied food options. We are pleased to see that the rule reflects recommendations made by the Institute of Medicine (IOM) report, WIC Food Packages: Time for a Change. These revisions are grounded in sound science, aligned with the 2005 Dietary Guidelines for Americans, support the current infant feeding practice guidelines of the American Academy of Pediatrics and better enable the establishment of successful long-term breastfeeding. This proposal finally brings the WIC Food Packages in line with current dietary science and will have a positive impact on the health of women, infants, and children in Texas and throughout America.

We ask that you consider the following points as you develop the final rule.

1. Food Package I: Infants < 6 months

Regarding the proposal to tie the maximum issuance of infant formula to breastfeeding practice:

~~We support maximum allowances for each category (fully breastfed, partially breastfed, and fully formula-fed).~~

We support that powder formula alone is recommended for partially breastfed.

We request that the current and proposed regulations be modified to count a breastfeeding woman whose high-risk infant is issued only Human Milk Fortifier as exclusively breastfed.

We support the following proposals:

Removing juice and infant cereal for infants four and five months old.

The proposed increase in formula for infants four and five months old, as follows: from 806 fl. oz. reconstituted concentrate to 884 fl. oz. (29 oz/day); from 800 fl. oz. Ready to Use (RTU) to 896 fl. oz.; and from 870 fl. oz. reconstituted powder to 960 fl. oz. (31 oz/day). However, we ask for clarification in the final rule regarding concentrating formula to a higher caloric level. If a prescriptive authority orders 24 kcal/oz or 27 kcal/oz formula or any concentration higher than the standard 20 kcal/oz. would issuance still be for the same amount reconstituted as those proposed for 20 kcal/ounce? Additional cans of powdered formula would be required to do this.

That infants less than one month old will be recognized either as fully breastfed or fully formula-fed and that no partially breastfed infant will receive formula until one month of age. However, Texas WIC shares the same implementation concerns as the National WIC Association and concurs with the recommendation that for breastfeeding mothers who request formula in the first month, additional breastfeeding support be provided by the clinics and where formula is deemed appropriate, clinics may provide a small amount of powdered formula. The final rule language should clarify that formula may be provided even if the mother has redeemed benefits for an exclusively breastfeeding package.

The proposal to disallow low-iron infant formula in food package I.

The reclassification of prescriptions of exempt infant formula under food package III.

2. Food Package II: Infants 6 to 11 months

We support the following proposals:

The change to delay complimentary foods and make infants eligible for food package II at age six months.

Establishing fully-breastfed, partially breastfed, and fully formula-fed with corresponding maximum formula amounts.

The elimination of juice and adding infant fruits/vegetables. Allowing fresh banana as a substitute for a portion of fruits/vegetables.

Providing more infant fruits and vegetables to fully breastfed infants than to partially breastfed or fully formula-fed infants.

The proposed maximum amounts of fruits/vegetables as follows: Fully formula-fed: 128 oz (32 four-oz jars); Partially BF: 128 oz (32 four-oz jars); and Fully BF: 256 oz (64 four oz jars).

Providing infant food meat to fully breastfed infants (pureed through diced and that broth or gravy is acceptable).

The disallowance of low iron formula in food package II.

The disallowance of infant cereal with added ingredients.

3. Food Package III - Medically Fragile Participants

Regarding Medical Foods designed for inborn errors of metabolism (FNS seeking comments), we support the use of medical food bars. We suggest FNS determine the maximum monthly allowance by using the protein equivalent to the amount of protein the formula provides.

Regarding the section that expands upon the restrictions when issuing a WIC formula in a Ready-to Feed (RTF) form, we support the rule as proposed; however, the final rule should clarify that RTF formula may be issued for infants with compromised immune systems (as in the case of premature infants), even though a powder alternative may be available.

We support the administering of exempt formulas to infants with qualifying conditions under food package III (i.e. move from food package I or II to III), but have some concerns.

Concern: We believe the condition/term "failure to thrive" as a qualifying condition for food package III should be removed since there is no standardized definition.

Concern: USDA should clarify the language in the final rule regarding the food packages' purpose and scope. We support the purpose of food package III for consolidation of all medically fragile individuals into one package to facilitate management and tracking of the benefits and cost of providing supplemental foods to these participants. But, we are concerned primarily about the protein hydrolysate class of formulas, which are commonly prescribed for milk and soy allergies and/or malabsorption. These products are currently considered exempt and the final rule should make it clear they are still classified as such for the purpose of qualifying for food package III. The proposed rule indicates that infants and/or children would have to be diagnosed with severe food allergies, requiring an elemental formula, such as Neocate, to qualify for food package III.

Concern: If participants do not receive foods (e.g., totally tube-fed or developmentally delayed), we recommend they receive more formula even if the formula is not an exempt formula. In addition, milk and soy-based formulas should also be provided in food package. III for premature infants until adjusted age one, and for other conditions requiring these formulas. USDA should clarify and address this in the final rule.

Concern: There does not appear to be an appropriate food pkg. for infants (6-12 months old) receiving 100 percent of their nutrient requirements via tube-feeding that will provide adequate amounts of formula; please note that these infants may not qualify for Medicaid. The food package as described in the proposal would not meet the needs of a totally tube-fed infant who could not use the baby food offered in the food package.

Concern: Another situation would be where a 6 - 11 month old who for developmental or medical reasons would not be able to consume baby foods. This infant would only be issued 22 ounces of formula per day. We recommend the final rule allow for providing more formula to those infants in lieu of the infant food.

Concern: We are also concerned that only issuing 20 ounces of a potentially very expensive formula is not enough supplement, even though WIC is a supplemental program. We recommend the final rule allow providing extra/more formula to those infants, who for developmental, medical, or whatever reason cannot eat baby foods. This would include premature infants, whose corrected age is such that baby foods would not yet be recommended. Since the baby foods would not be utilized in such cases, suggest that additional formula be issued in place of foods.

Regarding the clarification in the rule that medical foods are designed for children (12 months and older) and adults; therefore, infants served under food package III cannot receive medical foods:

We oppose restricting medical foods from infants under food package III. Some medical conditions, such as decreased renal function, inborn errors of metabolism, cardiac conditions, poor weight gain, and the need for increased calories or protein exist that require the use of an infant or exempt formula in addition to a medical food. Detailed examples: 1) for an infant whom the doctor would like to receive 30 kcal/oz. formula by concentrating the formula to 24 kcal/oz. and adding Polycose or MCT oil, or both, to increase calories. This keeps the osmolality lower than if formula was simply concentrated to 30 kcals/oz. MCT oil is an easy to absorb oil for infants with fat malabsorption; 2) Duocal, a carbohydrate and fat supplement, is sometimes prescribed to increase calories in infant formula or in baby foods; and 3) A protein modular, such as Beneprotein, may be used to increase protein for an infant in some circumstances, such as for infants with cystic fibrosis. It is possible to issue amounts of both that do not exceed the maximum amounts allowed by regulations. We would like to see these allowed for infants with appropriate diagnosis and documentation.

Regarding prescription requirements, FNS should consider our recommendation that physician-prescribed amounts of formula and/or supplemental foods per day be removed from the prescription documentation requirements. Many health care providers are unable to keep up with the ever changing formula industry and would not be able to site appropriate amounts of the various formulas/supplemental foods needed per day.

4. Food Package IV: Children age 1 up to age 5

We support the following

Reducing the amount of milk from 24 quarts to 16 quarts;

• That cheese may be substituted for up to three quarts of milk. Because cheese is a popular benefit, we recommend that State agencies choosing to substitute one pound of cheese in the food package be allowed to round the one quart up to a half-gallon or round down to 15 quart equivalents total.

• The modification/clarification of reconstitution rates of dry and evaporated milk.

• The move to fat-reduced milk for children ages 2 and older but request that the final rule allow State agencies the ability to provide fat-reduced milk to children less than 2 years of age for one year olds with weight for length above the 95th percentile or with health problems (heart or cholesterol issues, for example) made worse by whole milk intake with appropriate medical documentation. We also request the final rule allow State agencies the ability to provide whole milk to children older than 2 yrs of age who are underweight or who are at risk for underweight.

• The addition of whole grain bread (and allowed substitutions).

• The reduction from 2.5 dozen eggs to one dozen eggs as protein is no longer a priority nutrient and this is consistent with the 2005 Dietary Guidelines for lowering cholesterol.

• The ability to substitute canned beans for dry beans at the rate of 64 ounces per pound, but only if State agencies continue to have the option of choosing canned or dried beans.

• The “51% whole grains” requirement, but have a concern that the “51% whole grains” requirement may limit too severely the variety and types of cereals that would be WIC-eligible. In particular, we are concerned about the elimination of corn & rice products used for allergen sensitivity reasons. We concur with the NWA recommendation that in cases when a participant presents with a medical diagnosis warranting a “wheat-free” cereal, that a special package be issued that includes cereals that meet the current iron and sugar criteria, but not the whole grain proposed criteria. In terms of the 51% by weight, it appears according to the industry comments on the proposal that there are some inequities in the whole grain requirement. We sincerely hope that USDA will consider a reasonable approach to these inequities.

Regarding soy beverages, we support the addition of soy; however, we have two concerns:

• Concern: We understand that soy beverages are required to be of the equivalent nutrients as milk; therefore, we do not believe it imperative that a physician write an Rx and/or be alerted that a child is on soy. The consumption of soy beverage for children can be a cultural/personal preference as well as a medical necessity. Since state policies and procedures for services and follow-up to medically diagnosed conditions will continue to be in place, this proposed rule will place an undue burden on State systems and delay access to an important calcium source for WIC children.

• Concern: Currently, it appears that the nutritional content of most soy beverages available do not meet the requirements outlined in the proposal for a nutrient standard of 8 grams of protein and 349 milligrams of potassium per 8 ounce serving. We agree with the recommendation of the National WIC Association (NWA) that the specifications for protein and potassium in calcium-fortified soy beverages

follow the FDA and industry standards for protein at 6.25 grams minimum and for potassium at 250 milligrams per 8 ounce serving. Since protein is no longer a priority nutrient and the addition of fruits and vegetable contribute to the food packages' potassium content, this adjusted specification will not affect the nutritional needs of participants who substitute soy beverages for cow's milk.

We support the juice reductions in general, but have serious concerns about package sizes as follows:

The juice maximum amounts authorized for children limits the selection of juice containers. Children authorized 128 fluid ounces only would be able to have juice in 32 ounce containers or 64 ounce containers. No frozen juices would be possible.

Many clients prefer frozen juices and frozen juice retains its Vitamin C content more so than plastic containers. Data from Texas WIC client preference surveys indicate approximately 25% of our clients prefer frozen juice. In addition, actual purchase information by Universal Product Code (UPC) data from the Texas electronic benefits transfer (EBT) shows this same percentage.

The mix of containers (32/48/64 ounce Fluid and 6/12 ounce frozen) becomes problematic with EBT considering the food packages for the family are aggregated on the card. The quantity for the family would require the unit of measure be at the fluid ounce. A pregnant mom, with an 18 month old and a 3 year old, would have 400 fluid ounces loaded to her card. If she purchased only 48 fluid oz and 12 oz frozen containers, she would end up forfeiting 16 ounces.

Therefore, we strongly recommend instead of mandating the maximum issuance of 96, 128, and 144 ounces of juice, USDA consider allowing a range. Postpartum 92 - 96 fluid ounces; Pregnant/Breastfeeding 138 - 144 fluid ounces, and children 92-138 fluid ounces. Note: this comment is also included concerning women participants in this document in the section on Food Packages V, VI, and VII.

Regarding adding a \$6 monthly voucher for fruits & vegetables:

We support adding fruits and vegetables. However, we understand the Institute of Medicine considered the use of a maximum quantity of pounds of fruits & vegetables, rather than a cash value. We strongly recommend this be reconsidered as an option for States; i.e., the latitude to prescribe a not to exceed quantity rather than a not to exceed dollar amount.

5. Food Packages V, VI, and VII

Regarding conditioning eligibility for Food Package V on breastfeeding practice, we oppose the proposal that mothers who request more formula than the maximum amount allowed for partially breastfed infants will no longer be eligible for food package V. If a breastfed infant needs more than 10 ounces of formula per day, we believe WIC should support and acknowledge the fact that the mother is making the best choice for her baby by continuing to breastfeed and provide her with either a postpartum food package or a partial breastfeeding package. For example, a breastfeeding woman who works full-time in a setting that is not private enough for pumping at work, will only receive a half-

package of formula (10 oz. per day) and her infant is away from her all day, most likely in a day care setting. She is trying her best to breastfeed in the morning before work and at night, but can't provide enough breast milk to send her child to day care all day because she doesn't have the luxury of pumping at work. It is likely that, among the WIC population, the types of jobs held by WIC clients tend to be in settings that do not offer pumping at work.

We support the following:

- Reassigning food package VI up to six months postpartum.
- Reducing the prescribed amounts of milk in food packages V, VI & VII.
- The cheese substitutions in food packages. V, VI & VII.
- The proposal that cheese and tofu combined can replace no more than four quarts of milk except for women with documented medical needs may be prescribed in excess of the 4 qt max.
- The proposal that no more than one pound of cheese may be substituted for milk at the unchanged rate of one of pound cheese for three quarts milk.
- Soy beverages allowed as a substitute for the entire milk allowance.
- That yogurt was omitted for cost reasons.
- The changes in the substitution rates of evaporated and dry milk to ensure that participants receive the same maximum monthly allowance of milk (reconstituted) as those issued fluid milk.
- Adding one pound of whole grain bread at the State agency's option, with the same concerns identified in this document under the topic of Food Package IV.
- The proposed substitutions for whole grain bread: brown rice, bulgur, whole grain barley, and soft-corn or whole-wheat tortillas.
- Reducing the maximum egg prescriptions.
- The ability to substitute canned beans/peas for dry beans/peas at the rate of 64 ounces per pound, but only if State agencies continue to have the option of choosing canned or dried beans/peas, an option currently only allowed for homeless participants.
- The addition of 18 ounces of peanut butter to Food Package V.
- The addition of adding either one pound of beans or 18 ounces of peanut butter to Food Package VI.
- The proposal to authorize 30 ounces of canned fish, including light tuna, salmon and sardines with a State agency option to choose fish varieties and packaging.

We support calcium-set tofu and calcium-fortified soy beverage allowed as new milk substitutes, but have the following concerns:

Concern: Calcium-set tofu does not appear to be readily available in Texas.

Concern: There appears to be a very limited availability of calcium-set tofu or other tofu in the 1-lb packages.

We ask USDA to consider these problems and how they can be remedied so that tofu can continue to be offered.

We support the juice reductions in general, but have serious concerns about package sizes as follows:

The juice maximum amounts authorized for pregnant, postpartum, and breastfeeding women (144 and 96) limit the selection of juice containers to 48 ounce fluid, and 6 ounce/12 ounce frozen.

Many clients prefer frozen juices and frozen retains its Vitamin C content more so than plastic containers. Data from Texas WIC client preference surveys indicate approximately 25% of our clients prefer frozen juice. In addition, actual purchase information by Universal Product Code (UPC) data from the Texas electronic benefits transfer (EBT) shows this same percentage.

The mix of containers (32/48/64 ounce Fluid and 6/12 ounce frozen) becomes problematic with EBT considering the food packages for the family are aggregated on the card. The quantity for the family would require the unit of measure be at the fluid ounce. A pregnant mom, with an 18 month old and a 3 year old, would have 400 fluid ounces loaded to her card. If she purchased only 48 fluid oz and 12 oz frozen containers, she would end up forfeiting 16 ounces.

Therefore, we strongly recommend instead of mandating the maximum issuance of 96, 128, and 144 ounces, USDA consider allowing a range. Postpartum 92 - 96 fluid ounces; Pregnant/Breastfeeding 138 - 144 fluid ounces, and children 92-138 fluid ounces.

Note: this comment is also included concerning child participants in this document in the section on Food Packages IV.

We support adding \$8 monthly voucher for fruits & vegetables with one significant concern. We understand the Institute of Medicine considered the use of a maximum quantity of pounds of fruits & vegetables, rather than a cash value. We strongly recommend this be reconsidered to give states implementation flexibility for their infrastructure and current systems.

Our other comments on the fruits/vegetables voucher are as follows:

The final rule should clarify whether or not FNS envisioned participants receiving money in change from a cash voucher. The proposal is silent.

We support allowing dried fruits and vegetables at the State agency's option.

We strongly support keeping it optional that farmers' markets can participate in redemption of the WIC fruits and vegetable benefit. State agencies must have this option to decide.

We concur with the NWA recommendation to provide an additional \$2 to the fruit and vegetable vouchers for the fully breastfeeding woman's

food package in order to bring the cash-value vouchers to the original IOM recommended amount of \$10 per month. The increased dollar amount would provide an additional incentive for women to breastfeed.

We concur with the NWA recommendation that FNS should seek additional funding in its future budget requests to allow for full implementation of the IOM recommendation of \$10 cash-value instruments for all women and \$8 for children. Cutting corners with the fruit and vegetable instrument will lead to reduced health benefits for WIC mothers and children. WIC's success has been in saving long-term health costs. Making this modest investment will assure healthcare savings in the future.

We oppose that a cultural preference for the use of tofu for more than one-pound allotments is only authorized with medical documentation because this defeats the meaning of honoring a cultural preference. "Cultural preference" means no medical documentation should be needed.

6. Other Provisions

We strongly support the language that clarifies the right of the State agency to impose restrictions on WIC foods, including:

- the right to exclude particular products by brand or variety;
- the right to set standards that are more restrictive; and
- the right to take into account issues of cost, nutrition, statewide availability, and participant appeal in setting these restrictions.

We strongly support the statement by FNS in the Preamble that permitting State agencies to set additional criteria consistent with their own market and population profiles encourages the development of State agency food lists that meet or exceed nutritional standards, maintain participant acceptance and control costs. We urge FNS to keep this language in the final rule.

We support the following:

- The continuance to allow individual tailoring.
- Rounding up for infant formula and infant foods but the proposed methodology for the State rounding option will result in a family receiving a different number of cans of formula each month. This will prove confusing, give rise to complaints, and could even be viewed as discriminatory by WIC families.
- The use of reconstituted fluid amounts.
- The identification of Full Nutritional Benefit (FNB) provided by infant formula as the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate and at least the equivalent of powder for the food package category and infant feeding option.
- The amendment to the definition of participation to change to the sum of (1) Number of persons who receive food instruments or foods; (2) Number of infants who did not receive food instruments or foods by whose BF mother

received food instruments or food; and (3) Number of BF women who did not receive food instruments or food but whose infant received food instruments or food.

That authorized vendors are required to carry a minimum of two varieties each of fruits and vegetables, in any combination of fresh and processed and that the State agency may establish different minimums for different vendor peer groups.

That cash-value vouchers for the implementation of fruits and vegetable benefits shall be subject to the provisions of §246.12 as described in the preamble.

The substitution of pasteurized liquid whole eggs or dried egg mix for fresh shell eggs and that hard-boiled eggs where readily available are allowable for homeless participants, if it is a State agency option.

The adoption of the new term "breakfast cereal."

The clarification that reduced fat peanut butter is a State agency option alternative for regular peanut butter in Food Pkgs. III, IV, V, VI, and VII.

The requirement that State agencies make at least two fruits and two vegetables available in each authorized food package, and we agree with FNS's expectation that more than two varieties each be authorized with State agencies offering the widest variety possible.

The requirement to advise participants that foods are issued for their personal use only and foods are not authorized for participant use while hospitalized on an inpatient basis.

Regarding Food packages I and II global on changes in infant feeding practices by assignment to one of three feeding options (Fully-formula fed, partially BF and fully BF):

We support but ask that FNS clarify that a mother/infant on a fully breastfed package can return to WIC during the month and obtain a formula package if necessary.

While the additional nutritional needs of a mother breastfeeding multiple infants have been addressed in the IOM recommendations, USDA may want to consider the availability of a 3/4 package of formula in addition to the mother receiving a full package.

Regarding the provision that the full maximum monthly allowance of foods in all packages must be made available if medically or nutritionally warranted, we support with two concerns:

Concern: State agencies need the flexibility with control of package sizing.

Concern: In addition, if the food industry does not make some package size changes, certain foods will not be available in the maximum monthly allowance.

Regarding the requirement for the State agency to coordinate with other Federal, State or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC-eligible medical foods and, at a minimum, must coordinate with Medicaid, we have a significant concern. We

are concerned that coordination not be required prior to certifying and issuing formula because the coordination could cause a barrier.

There doesn't appear to be an appropriate food package for infants (6-12 mo old) receiving 100% of their nutrient requirements via tube-feeding that will provide adequate amounts of formula; please note that these infants may not qualify for Medicaid.

We are concerned about the implementation of coordination with Medicaid.

We want to be certain that there are no first payor requirements that could prevent us from serving a participant prior to Medicaid approval.

We are inalterably opposed to prohibiting State agencies from petitioning FNS for new food package substitutions. Nothing in the law prohibits this. Congress neither explicitly nor implicitly acted to limit the State agencies' ability to propose food package changes. Therefore, we see no reason for FNS to take this right away from State agencies. Further, if FNS has only received 10 proposals in decades, it can hardly be argued it has been an administrative burden. It is essential that States retain this right to keep pace with the needs of their participants.

Regarding the proposal that ends the State agency practice of categorical nutrition tailoring, we are also inalterably opposed that State agencies will no longer be allowed to construct standardized sets of food packages for WIC subpopulations with common supplemental nutritional needs. It is essential that States retain this right.

Regarding the cash value voucher for fruits and vegetables, we have significant concerns that the final rule needs extensive clarification as to how this would work with the mandates of the Interim Rule on Vendor Cost Containment. The State agency must ensure that the payments to above-50-percent vendors per food instrument do not exceed the average payments to regular vendors per food instrument. We understand this applies to all food instruments. An example of one issue we do not see addressed is the situation where, for instance, a participant redeems a \$6 value cash voucher at an above-50-percent vendor for \$5.98 while another participant redeems a \$6 value cash voucher for a lower amount of only \$5.65 at a regular vendor. If more participants redeem cash vouchers for full value or close to full value at above-50-percent than participants who redeem them at regular vendors for less than full value, it appears the state would potentially not meet the cost neutrality standard unless the above-50-percent vendor's payment was reduced or the amount over the regular vendor average redemption amount was recouped later. This makes no sense. It defeats the purpose of an open-ended cash benefit and would probably be viewed by all vendors, but particularly by above-50-percent grocers, as unacceptable and discriminatory. Also, if the implementation solution in an Electronic Benefits Transfer (EBT) environment will mean selecting all the types of fruits/vegetables to be offered (and we assume states want a large variety), setting an individual price for each type (apples, oranges, spinach, melons, etc.), and then ensuring that each one of those reimbursement amounts are subject to the vendor cost containment restrictions and recoupments for overpayments once a statewide average is calculated, we have a problem. The additional complexity and administrative burden to both the state

agency and vendors for complying with cost containment and recoupments of overpayments to above-50-percent vendors becomes huge. Wha

We also have concerns that the proposed rule regarding a cash-value benefit for fruits and vegetables did not clearly define the definition of one-to-one reconciliation in the WIC cash environment, including in an off-line or on-line EBT environment using category and subcategory. It is not clear at all if reconciliation would be equated to what normally constitutes reconciliation in an electronic checking environment. Different implementation issues would arise for various alternative methods of implementing the cash-value benefits (e.g. EBT, magnetic stripe, on-line; EBT smart card, off-line, prepaid debit cards; cash coupons etc.) depending on the definition of reconciliation.

The final rule on the cash value fruits and vegetable benefit also must clarify the following:

- Whether or not the WIC participant can receive cash back (change) if not all of the cash value benefit has been used.

- Whether or not the WIC participant can pay additional cash towards the purchase of fruits and vegetables if the purchase amount exceeds the amount on the cash instrument.

Implementation Considerations (particularly vis à vis EBT)

In the supplementary information to the proposed rule, USDA indicated it is seeking comments from State agencies on the type and scope of administrative burden that may be associated with implementing the provisions of the proposed rule. We believe the proposed revisions to the WIC food packages may require moderate to very significant changes to states' computer systems. We believe it is critical that the final rule and USDA have enough flexibility to create one single critical path timeline for all major WIC MIS projects. That would include for Texas (and likely in other states as well) implementing EBT, moving to a new MIS State Agency Model (SAM) system, implementing vendor cost containment, and implementing the new food packages all at the same time. The food package changes will not be done in a vacuum. USDA must take this into account.

Of utmost importance for USDA to take into account is that a one-year implementation timeframe is extremely aggressive, particularly for Texas because we are operating two food delivery systems - paper voucher and EBT - as we roll out EBT statewide. If the final rule mandates without exception a one-year implementation timeframe, Texas will have to modify two food delivery systems in parallel, which means increased costs. Because we could not accomplish the changes in EBT in one year, we would have to re-equip our local agencies running EBT because we have disabled any voucher issuance capability. Printers and voucher stock would have to be issued to those agencies and that would have a cost. Our EBT cost benefit analysis would then be skewed because we have shown a decrease in systems cost by de-implementing the hardware and software associated with our legacy voucher system. This includes a large proprietary server system and software at the State agency as well as equipment such as the aforementioned

impact printers at our WIC clinics. Use of a paper cash value instrument would require us to maintain legacy systems beyond what was envisioned or undergo a costly redevelopment of the system to allow it to run on the WIC EBT server platform.

In Texas, implementing the cash value benefit for fruits and vegetables via a paper voucher would be only for a limited time. Issuing paper vouchers is going backwards for the WIC community and particularly for states already implementing EBT in more ways than one. In a state such as Texas that currently processes two million paper vouchers each month, the addition of one to four additional paper vouchers per woman/child would mean as many as an additional 2.5 million vouchers per month. As USDA seeks funding from Congress, the increased administrative cost for State agencies to issue and process new food vouchers should be factored in.

USDA must recognize that for states with an Electronic Benefits Transfer (EBT) food delivery system in place, the level of effort to implement this change varies depending upon the manner in which WIC prescribes and allows redemption of this food. A number of the foods being proposed may have only limited impact upon WIC EBT systems. For example, foods such as baby food, bread and tofu could be added as new food categories and subcategories. As long as all of the items offered have UPC codes, the method of food issuance and redemption remain much the same as currently performed. Allowing substitution of products in the grocery store and/or use of both specific and broadband subcategories for certain UPCs would, however, complicate the implementation. Therefore, overall a limited to moderate level of systems change would be required depending on the implementation solution and requirements.

Care would need to be exercised regarding any changes to milk issuance and redemption. Grocer Electronic Cash Register (ECR) systems perform benefit optimization (aggressive redemption) in which benefits are redeemed from specific subcategories before using a broadband subcategory. The computer programming to accommodate this proved to be complicated for many systems developers. Any change in food issuance that modifies the benefit optimization may result in very significant changes to Grocer ECR systems.

Of all of the proposed changes, the issuance and redemption of fruits and vegetables has the most potential for requiring significant changes to WIC EBT systems. The impact of this change is highly dependent upon the types and packaging of the fruits and vegetables to be offered.

We strongly urge USDA to sponsor a meeting among the states currently using WIC EBT systems and the USDA consultant, Booz-Allen Hamilton, to design an approach that can work within the current Universal Product Code (UPC) environment. A common design and reference implementation should be produced that can be incorporated into the State Agency Model (SAM) system developments. Grocers and representatives from the Point of Sale (POS) industry should also participate.

Regarding implementation methods in EBT, the simplest method is for WIC to only authorize fruits and vegetables that are packaged with specific weights and labeled with

UPC codes. The issuance of these benefits would be based on the weight of the product (e.g. ounces, pounds) rather than the cost of the product. This would allow the redemption of fruits and vegetables in the grocery store in a similar manner as currently done for other food categories. Like other food categories, a "not to exceed" dollar amount would be associated with the unit of measure (e.g., ounce, pound). Clinic systems and state agency host systems would require a moderate amount of change to incorporate the new food types and changes in food packages, when testing and training are taken into account. Grocer systems would require only limited changes to implement this. Depending upon the exact specifications, these changes may have only a limited to moderate impact upon these systems. However, the variety of fruits and vegetables would be limited to those with UPC codes.

Next in level of systems complexity is the use of PLU codes and random weights for redeeming fresh fruits and vegetables. This could be a very significant system change. WIC would need to work with the grocer industry to ensure standardization of the PLU codes associated with fruits and vegetables so that they are consistent among all grocers. (Most grocers already use standardized PLU codes.) The industry would also need to ensure that PLU codes are unique from the values used for UPC codes. Grocer integrated systems would need to incorporate the ability to allow redemption of random weight items. Grocer integrated systems would need to incorporate the ability to allow redemption of random weight items. During WIC EBT certification, grocer system developers have been informed of the potential need for this change. Depending upon the grocer industry's ability to implement their changes, the WIC Clinic systems and state agency systems would require a moderate to very significant level of change to incorporate the new food types and changes in food packages as well as the updates to reference files for entry of PLU codes. Depending upon the exact specifications, these changes may have a moderate to significant level of impact upon these systems.

The most complex change would be to allow redemption of fruits and vegetables based upon a specific dollar amount. Very significant changes would be required for all aspects of WIC EBT systems. The data stored on WIC smart cards would need to be changed to include electronic purses to securely store cash value. Grocer integrated systems would need to develop new modules to handle the cash value decrement from the card versus the current use of category/subcategory of product. Additional changes would be required to determine the types (UPCs / PLUs) of product that are allowed for redemption with this cash value. WIC Clinic systems would require significant amounts of change to incorporate the issuance of cash value to the smart card. State agency systems would require significant changes to track the dollar amount of issuance versus redemption and ensure that proper amounts are restored to the card when cards must be reissued (e.g. replace lost card). Depending upon the exact specifications, these systems may require major redesign and development to accommodate these changes.

Costs for EBT implementation: As previously stated, a moderate to significant programming effort would have to be undertaken in Texas to change the state MIS system as well as 19 different grocer commercial systems. Our EBT solution incorporates different store/industry systems that are now programmed to integrate EBT

into the store system (e.g. IBM ACE, IBM SA, Fujitsu-ISS-45, etc.). In addition to programming costs there will be network and hardware costs, but these cannot be estimated until details are decided on the implementation solution for a cash-value benefit for fruits and vegetables in an EBT environment. USDA needs to be aware of these costs.

WIC EBT systems can be modified to address the proposed food package changes; however, the implementation effort would vary greatly depending upon the types of foods and their packaging. USDA would need to provide both adequate lead time and funding to ensure that all systems are fully tested and proven ready to implement these changes.

Cost Neutrality

Analysis of Texas food costs, redemption patterns, and a preliminary survey to the extent possible at this time of prices for new foods did not prove the proposed changes to be cost neutral for Texas. Rather, our analysis shows an estimated increased cost of more than \$2.6 million annually. These costs represent food costs only and not implementation costs associated with information technology systems, nutrition education materials, training, etc.

We strongly urge FNS to take this into consideration.

Our methodology and assumptions were:

- We used actual Texas May 2006 participation numbers, redemption rates per food type (e.g. milk, cheese, juice, cereal, formula, beans, peanut butter etc.), and average prices we paid vendors for each food type that we offer and included in our analysis. For new foods, we surveyed some of our large chain stores for current prices (consequently, this may represent a low estimate since these large stores do have the lowest prices).

- We used the May 2006 percentage of clients choosing peanut butter versus beans (42% and 58% respectively)

- We used a mix of 83% powder formula and 17% concentrate based on our May 2006 issuance data. Our final numbers represent post-rebate calculations.

- We arbitrarily estimated the percentage of clients who might choose bread, tortillas, or brown rice as 45%, 45% and 10% respectively. In reality, we believe almost all clients will choose bread as it is the most expensive item of the three and is likely to be the most popular by far. This would tend to make our analysis on the low side for increased cost.

- We used the 87.5% redemption rate for the fruits/vegetables cash-value option that FNS reported using (\$5.25 for children and \$7.00 for women).

- We assumed our partially breastfed infants would all receive a full-formula package under the new proposal.

We did not attempt to estimate the number of substitutions of tofu or soy that might occur.

We did not attempt to estimate the number of participants who would choose sardines or salmon instead of tuna.

We used a quantity of milk equivalent to one less quart than FNS is proposing because we hope FNS will respond favorably to our comment that issuing that extra quart is too costly.

We used a quantity of juice that is less than what is proposed because we hope FNS will respond favorably to our comment that the proposed quantity does not allow for issuance of frozen juice to children and limits the options for women.

We estimated a 90% redemption rate for infant foods.

In the following data, costs and savings are shown by type of food package.

Pregnant/Breastfeeding	Monthly Change = (\$22,626.36)
Enhanced Breastfeeding	Monthly Change = \$7,304.94
Postpartum	Monthly Change = (\$75,550.67)
Child	Monthly Change = (\$438,120.46)
Infant 100% BF	Monthly Change = \$86,389.61
Infant Formula Fed	Monthly Change = \$666,623.40
TOTAL MONTHLY CHANGE =	\$224,020.46 ANNUAL CHANGE =
	\$2,688,245.52

In conclusion, we look forward to working with USDA and the rest of the WIC community to implement these excellent food package improvements over the next few years. If planned carefully and leveraged by strategic partnerships with grocers, nutrition advocates and WIC families, the implementation of the new WIC food package could drastically improve community food security, address the obesity epidemic, and make healthy food choices easier for millions of low-income households - even outside of WIC. Taken together, this regulatory proposal will ultimately have a positive impact on the health of women, infants and children in Texas and all states.

Submitted on behalf of:
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